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Note if anything has been removed from thesis.

**Appendix G p488-end and Appendix D p464-5, published papers. Questionnaire and model p278-280.
Appendix B, data collection tools.**

When referring to this work, the full bibliographic details must be given as follows:

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**An Evaluation of the Development
and Implementation of a Clinical
Guideline for Nurse Led Extubation
of Adult Coronary Artery Bypass
Graft Patients**

By Claire Alicia Hawkes.

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award of Doctor of Philosophy, by Oxford Brookes
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ABSTRACT

Research Question

Does standardising nursing practice through the implementation of a clinical guideline for extubating adult cardiac surgical patients early improve patient care?

Aims

Evaluate the development and implementation of a clinical guideline for nurse-led extubation of adult cardiac surgical patients at one centre in the United Kingdom.

Objectives

1. Provide a systematic overview of the evidence base for early extubation (Hawkes et al., 2003).
2. Quantify the impact on professional practice of standardising care through the use of the guideline (interrupted time series (ITS)).
3. Explore the results of the ITS and identify important factors for the successful implementation of the guideline (qualitative study).

Methods

A mixed methods approach in a single case study was used. New evidence in the form of a systematic review, including a meta-analysis, of existing evidence for early extubation was used to meet Objective One. An ITS study was used to quantify the impact of implementing the guideline. The third objective was met through a qualitative study drawing on applied practitioner ethnography. The last two parts contribute

unique evidence because there was no such existing evaluation of a nursing guideline for extubating cardiac surgical patients.

Analysis

The systematic review's meta-analysis used relative risk and weighted mean differences. The ITS analysis used exponential models to compare predicted values with actual values to assess the impact of the guideline. Qualitative data were analysed to identify themes, using the framework approach (Ritchie and Spencer, 1994).

Results

Early extubation reduces intensive care unit and hospital length of stay; the evidence for its impact on mortality and morbidity is weak. Evidence to support various decision making processes for early extubation is also lacking. The ITS demonstrated no changes in the outcomes studied. The guideline developed was a consensus of existing practice. However, while it did not change patient care, it maintained standards in a changing environment.

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CHAPTER ONE

BACKGROUND TO THE STUDY

The organisation and delivery of health care has been an area of increasing interest to researchers and policy makers over the last twenty years. There is a growing realisation that this area of research should be developed and funded alongside biomedical and health technology research. For example, in the United Kingdom (UK), the Service Delivery Organisation programme has been established by the Department of Health (SDO, 2005). The premise behind the need for this type of research is the understanding that it is not only the development of effective treatments and therapies, but also how they are organised and delivered to patients, which contributes to their effectiveness. The development and implementation of a clinical guideline illustrates these points clearly. The content of a guideline benefits from health technology research, which itself may have been developed from biomedical research. This research used in a guideline has the potential to improve clinical practice, patient or service outcomes, however, the effectiveness of the implementation of the guideline is also a significant factor in whether the original research will improve clinical practice, patient or service outcomes.

Evaluation research is a way of studying the service delivery and organisation of health care innovations. This study is evaluation research. It aims to examine the effects of a health care intervention, i.e. the implementation of a clinical guideline for nurse-led early extubation of adult cardiac surgical patients. Early extubation is removing the patient's breathing tube after ending mechanical ventilation, usually within eight hours of surgery. This study also attempts to examine the circumstances in which the guideline was implemented and to assess the effectiveness of the implementation (Bond, 2000). It, therefore, aims to evaluate both the effectiveness of an intervention (early extubation of

adult cardiac surgical patients) and the effectiveness of the implementation of a clinical guideline for this intervention. This thesis may be considered a summative evaluation (Bond, 2000) because it aims to present information about the effectiveness and value of a service delivery innovation (a guideline for extubation of adult cardiac surgical patients).

Evaluation research commonly makes use of various research methods and may consist of evaluations of one or more cases to achieve its aims. Using a variety of research methods is often considered to strengthen a research study design by providing evidence about the subject under investigation from different sources, thereby increasing the internal validity of the study (Yin, 1994). One of the values of case study research is that it offers the opportunity to study a phenomenon in its natural environment. In this case the implementation of a clinical guideline in a specific hospital unit (the research site).

There are three linked parts to the study, each using a different methodology. A systematic review of the literature on the safety and efficacy of early extubation for adult cardiac surgical patients contributes to the evidence base for the clinical guideline and, more widely, to healthcare (see chapter four). An interrupted time series study aims to quantify the effects of implementing a clinical guideline for extubating cardiac surgical patients at one centre in the UK (see chapter five). A qualitative study, which draws on applied practitioner ethnography (see chapter six), explores the circumstances of the implementation.

Several studies have shown that early extubation of cardiac surgical patients appears safe without increasing the incidence of morbidity compared to conventional postoperative ventilation times of twelve or more hours (Westaby et al., 1993, Chong et al., 1993, Cheng, 1995 and Cheng et al., 1996a). Early extubation is seen as a way of reducing Intensive

Care Unit (ICU) length of stay and therefore hospital length of stay, with resulting cost savings (Corsetti and Perry, 1998 and Zevola and Maier, 1999). Nurse-led early extubation has been demonstrated to be safe in some studies and has been argued to contribute to reducing times to extubation for routine cases (Westaby et al., 1993, Anderson and O'Brien, 1995, Davies, 1997 and Gale and Curry, 1999). The National Service Framework, Coronary Heart Disease, Modern Standards and Service Models (Department of Health, 2000a) sets out the United Kingdom (UK) government's targets for cardiac patients' treatment. This includes increasing the number of revascularization procedures (including coronary artery bypass grafting) carried out and reducing waiting lists for this type of procedure. Although the potential of early extubation to achieve cost savings and increased throughput of patients is attractive, particularly to help meet targets, the strength of the evidence base for early extubation of adult cardiac surgical patients had not previously been reviewed in a rigorous systematic review.

Using research evidence in the development of clinical guidelines is considered to increase their validity and reliability (Lohr and Field, 1992, Grimshaw and Russell, 1993, Graham et al., 2000 and Liberati et al., 2001). An area of difficulty for clinicians developing clinical guidelines is having the skills, time and other resources necessary to evaluate rigorously the evidence base for their proposed guideline. The Cochrane Collaboration (2005) provides high quality systematic reviews for healthcare interventions, on their electronic database, to aid clinicians in the process of using research evidence in their developments, such as implementing clinical guidelines. There was no systematic review of the safety and efficacy of early extubation for adult cardiac surgical patients, to inform the research site group's development of the extubation guideline. The systematic review conducted as part of this study, and published with the Cochrane Collaboration (Hawkes et al., 2003), could be used to inform future revisions of the research site guideline and is

available for anyone with an interest in early extubation for cardiac surgical patients. It also contributes new evidence about early extubation through a meta-analysis.

Using high quality research in clinical guidelines is one way of improving practice and patient outcomes. However, the process of implementing clinical guidelines also has an effect on their outcomes. Therefore, the need to evaluate rigorously the effectiveness of the implementation of a clinical guideline is important, but it is not always evident in the healthcare literature (Grimshaw and Russell, 1993 and Thomas, et al., 1999a). Thomas et al. (1999a) identified 18 studies (either randomised controlled trials, controlled before and after studies or interrupted time series analyses of the introduction of interventions) in the nursing and allied health professions literature, all of which were noted to have inadequate reporting of their methods. The poor quality of the research means that the authors' conclusions were tentative. They concluded that there was some evidence that guidelines are effective in changing the process and outcome of care provided by nurses and allied health professionals, but they cautioned against generalising findings to other professions and settings. They also identified the need for the development and implementation of clinical guidelines in these professions to be more rigorously evaluated in research projects.

Evidencing the effectiveness of clinical practice guidelines can be difficult in healthcare settings. Randomised control trials are generally seen as the most rigorous type of research study in health care from which findings may be generalised. However, it is not always possible to run such trials because of practical, ethical or resource constraints. Controlled before and after studies provide an alternative, but weaker form of evidence. A weakness of these studies is that the two groups are undergoing the usual treatment and intervention at different times. This makes it difficult to control for factors in the environment, which

may change over time, and may confound the results of the intervention on the outcome variables. An approach to strengthening before and after designs is to use statistical modelling techniques to assess the effects of confounding variables. One such type of modelling is interrupted time series. It has not yet been widely used in health care research, but there is an increasing interest among researchers because of its potential to help evaluate the effects of changes in the environment over time in before and after studies.

An interrupted time series analysis of before and after data collected to evaluate the effectiveness of the implementation of a clinical guideline contributes to the discussion on providing stronger research evidence for the effectiveness of clinical guidelines. This research also appears to be the first research study of the effects of a clinical practice guideline on the nursing practice of early extubation of adult cardiac surgical patients.

Qualitative data were also collected and analysed, drawing on applied practitioner ethnography, to provide a means of exploring the results of the interrupted time series in more depth. The findings of this analysis were also compared and contrasted with existing literature about clinical guidelines and the implementation of evidence in clinical practice, to establish their contribution to this debate. It also adds to the rigour of this evaluation study of the development and implementation of the extubation guideline by using more than one research method to investigate the topic.

The idea to investigate the effects of implementing a clinical guideline for early extubation of adult cardiac surgical patients arose from the researcher's experiences in clinical practice. The researcher had become interested in how nurses made their decisions to extubate patients because of observing a variety of practices, while learning the skill

herself. A local audit had identified longer extubation times compared to when the unit had opened about eight to ten years earlier. The lengthening extubation times, identified in the unit audit, stimulated discussion among the nurses and different practices among nurses were considered as a possible cause of this increase in extubation times. The nurses decided to update their clinical guidance as a result of these discussions and a unit review that identified the need to update written guidance. A project to develop a care pathway for routine cardiac surgery was also underway and the nurses considered that a clinical guideline for extubation would be useful to slot into the pathway. These developments provided the researcher with the opportunity to investigate the impact of the implementation of the clinical guideline.

The results of this study are available to inform the nurses' practice at the research site. The study also contributes to the wider debates about the effectiveness of clinical guidelines, about effective measurement of the outcomes of clinical guidelines and about the safety and efficacy of early extubation for adult cardiac surgical patients.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

There has been interest since the late 1970s (Klineberg et al., 1977 and Prakash et al., 1977) in extubating cardiac surgical patients in shorter time periods. This has become possible with developments in anaesthetic and surgical techniques. Traditional anaesthesia used high doses of opiates which depress the patient's respiratory function, causing them to require mechanical ventilation for 12 –24 or more hours. The use of shorter acting anaesthetics has meant it is possible for the patient to wake up quicker and resume spontaneous ventilation (breathing for themselves) (Lichtenthal et al., 1983 and Guarracino et al., 1998).

Improved surgical techniques have also contributed to shorter postoperative ventilation times. Faster surgery means shorter cardiopulmonary bypass (CPB) times (i.e. time on the heart lung bypass machine during surgery and shorter postoperative ventilation times). Improved techniques have resulted in shorter operating times. There is some evidence that longer cardiopulmonary bypass times may be associated with longer mechanical ventilation times (Westaby et al., 1993, Cheng, 1995, Hickey, and Cason, 1995 and Verrier et al., 1995).

During the 1990s, with increasing pressure to contain medical costs, early extubation (removing the patient's breathing tube after ending mechanical ventilation) for cardiac surgical patients has stimulated considerable interest. Early extubation is seen as a way of reducing Intensive Care Unit (ICU) length of stay and therefore hospital length of stay,

with resulting cost savings as well as offering the potential to increase the numbers of operations performed (Cheng et al., 1996b, Corsetti and Perry, 1998 and Zevola and Maier, 1999). Improved resource use is an important consideration for the provision of cardiac services, in light of the United Kingdom (UK) Government's recent targets of increasing the number of revascularization procedures performed and reducing waiting times for surgery (Department of Health, 2000a).

Early extubation has also brought opportunities for professional development and role extension. Nurse-led early extubation has been reported to be safe and has been argued to contribute to reducing times to extubation for routine cases (Westaby et al., 1993, Anderson and O'Brien, 1995, Davies, 1997 and Gale and Curry, 1999).

The literature on early extubation focuses on two key areas. Firstly, the safety of extubating patients early and secondly improvements in service provision to deliver the most efficient and cost effective care for cardiac surgical patients. Safety issues have included not only studies that compare early, or even immediate extubation, with conventional extubation, but also studies that have tried to identify which factors predict longer ventilation times after cardiac surgery. Service delivery has also received much attention, with the need to contain costs of cardiac surgery. In some centres, the establishment of a separate cardiac surgical recovery area (CSRA), rather than using intensive care unit (ICU) facilities, has been a radical step to improve service provision. It has been seen particularly as a way to enable more operations to take place where there has been pressure on ICU beds (Westaby et al., 1993 and Massey and Meggit, 1994).

Programmes to streamline routine cardiac surgery, in particular, have been advocated and they often use a multidisciplinary approach to implement the associated changes. Such

programmes often incorporate care pathways to facilitate the patient's journey through cardiac surgery departments, whether they have designated cardiac surgical recovery areas or not. These care pathways are often referred to as fast track pathways or accelerated care pathways, because they aim to provide quality cardiac surgery within a shorter time span than the existing services (Karski, 1995, Papadakos and Earley, 1995, Edwards and Hess, 1996 and Griffith et al., 1996).

Protocols or guidelines for early extubation play an important part in these programmes. Anaesthetic protocols using drugs that facilitate early extubation are also often an important part of the pathway. Protocols to guide the decision process of when to extubate patients has often led to nurses, or respiratory therapists (in the USA), taking on this role that was previously in the domain of medical staff (Gale and Curry, 1999).

The terms guideline and protocol and, to some extent, algorithm, policy and standards, are often used interchangeably by nurses (Mulhall et al., 1997). They are all terms connected with written guidance on practice issues. In this thesis the term guideline is used to describe written guidance regarding the decision to extubate a patient. In the literature review the terms guideline and protocol are used more interchangeably, following the choice of term by the authors of particular studies.

This literature review covers papers on extubation of adult cardiac surgical patients, looking at the safety and efficacy of early (within six, eight or ten hours of surgery) compared with conventional extubation times of 12 to 24 hours after surgery. The review also attempts to identify variables that affect ventilation times and to discuss service delivery considerations associated with early extubation.

The discussion of safety and efficacy is essential in assessing the evidence base of early extubation. The evidence base of any intervention is a key consideration when developing a guideline or protocol for a clinical practice (Lohr and Field, 1992 and National Health Service Centre for Reviews and Dissemination, 1994). Ventilation times can be affected by many variables that are not necessarily directly caused by cardiac surgery, such as some chest infections or a patient's pre-existing lung pathology. These extraneous variables could affect the results of the study if they were not sufficiently well controlled in the study design. Therefore identification of variables affecting ventilation times for cardiac surgical patients is crucial when attempting to identify outcome measures or exclusion criteria for an evaluation study, such as this.

The service delivery discussion looks at the effectiveness of early extubation in terms of programmes to change patient management to include early extubation, improvements in resource use and quality of care issues. Early extubation has been frequently implemented in centres using a protocol or guideline that is part of a care pathway. Care pathways cover the whole patient episode, in this case the admission to hospital for cardiac surgery. As discussed earlier, these care pathways are often known as 'fast track' pathways, protocols or programmes.

The Oxford Centre for Evidence-based Medicine's Levels of Evidence (for therapy, i.e. healthcare interventions) and Grades of Recommendation (Phillips et al., 2001) has been used to guide the assessment of the strength of the evidence base for each area of the literature on early extubation of cardiac surgical patients.

Figure 2.1a Levels of Evidence (From Phillips et al., 2001)

- 1a Systematic Review of Randomised Controlled Trials (RCT)
- 1b Individual RCT
- 1c All or none (met when all patients died before treatment became available, but some now survive on it; or when some patients died before treatment became available, but none now die on it)
- 2a Systematic Review of cohort studies
- 2b Individual cohort study (including low quality RCT; e.g., <80% follow-up)
- 2c Outcomes research; ecological studies
- 3a Systematic Review of case-control studies
- 3b Individual case-control study
- 4 Case series (and poor quality cohort and case-control studies)
- 5 Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”.

Figure 2.1b Grades of Recommendation (From Phillips et al., 2001)

- A Consistent level 1 studies
- B Consistent level 2 or 3 studies or extrapolations from level 1 studies
- C Level 4 studies or extrapolations from level 2 or 3 studies
- D Level 5 evidence or troublingly inconsistent or inconclusive studies of any level

The following literature review considers the safety of early extubation, risk factors for prolonged ventilation and service delivery aspects of early extubation.

2.2 SAFETY OF EARLY EXTUBATION

Establishing the safety of early extubation, when compared with conventional extubation, after cardiac surgery for adults, is crucial and has been the focus of research studies and papers supporting its use. Although there was not a systematic review of early extubation (the highest level of evidence (Phillips et al., 2001), several studies suggest that early extubation of cardiac surgical patients is safe, without increased incidence of morbidity and mortality, compared to conventional postoperative ventilation times of 10 -12 or more hours. There are several randomised controlled trials (RCTs) (regarded as grade A or B evidence by Phillips et al., (2001), a considerable number of observational studies, mostly using historical control groups (grade C evidence according to Phillips et al., (2001), and papers presenting audit data about early extubation (regarded as grade D evidence by Phillips et al., (2001). This section considers the available evidence for the safety of early extubation for adult cardiac surgical patients and evaluates its strength.

Cardiac surgery causes respiratory insufficiency and this, combined with the use of high-dose narcotic (or opiate) anaesthesia, which depresses respiratory drive, led to the establishment of overnight ventilation as standard practice in cardiac surgery.

Improvements in cardiopulmonary bypass, surgical techniques and particularly, changes in anaesthetic management during the late 1970s and 1980s, meant that patients could resume spontaneous ventilation shortly after completion of their surgery. This raised the question of whether patient outcomes would be affected adversely if patients were allowed to breathe for themselves much earlier following surgery. There was concern that the work of breathing at an earlier stage following surgery would increase the incidence of cardiac and respiratory complications.

2.2.1 Cardiac Complications

Mangano et al., (1992) found that postoperative myocardial ischaemia (the heart muscle is temporarily starved of oxygen because of a reduced supply or increased demand without an associated increase in blood supply) was related to adverse cardiac outcomes in coronary artery bypass surgery. As a result they investigated the role of analgesia in suppressing the stress response and resulting myocardial ischaemia in the postoperative period. They conducted a randomised controlled trial of two types of high dose analgesia included in the anaesthetic for coronary artery bypass surgery patients. They concluded that the most substantial changes in myocardial function occur in the early postoperative period (i.e. up to about 8 hours following surgery) and that intensive analgesia (including high dose narcotics, like morphine) could reduce the incidence and severity of ischaemia.

Anaesthetic techniques to enable early extubation (within six to eight hours of surgery) usually do not include high dose opiates for prolonged periods, so studies have been concerned to demonstrate that the effects of early extubation do not include greater incidence and severity of myocardial ischaemia.

2.2.1a. The contribution of observational studies and a literature review to the evidence base for the impact of early extubation on cardiac complications

Since the late 1970s there have been many reports from different institutions, of before and after studies concerning change of practice from conventional extubation (extubation after 8 to 10 hours following surgery and in many cases ventilation overnight following surgery) to early extubation. These observational studies tend to have historical control groups, some of which are matched cohorts. Generally, at least one of these cohorts' results is based on retrospectively collected data and so these studies are considered to provide grade C evidence (Phillips et al., 2001).

In the 1970s two important studies, albeit observational studies, found that early extubation did not appear to result in higher complication rates. These studies are important and have been influential because they were the first to report the possibility of early extubation. In 1977, Klineberg et al. published the results of a retrospective review of patient notes. In this observational, before and after study they reported a change in practice to early extubation, for low risk cardiac surgical patients. The change in practice had been successful without significant increases in morbidity and mortality rates, although incidence and severity of myocardial ischaemia were not reported. Prakash et al. (1977) reported findings from a study of 142 cardiac surgical patients that addressed concerns about the added work for the heart caused by resuming spontaneous ventilation. Of the 142 patients, 123 (c.86%) were successfully extubated within 3 hours of surgery. The authors concluded that any increased work of breathing, at an early stage postoperatively, did not adversely affect the patient's postoperative recovery and so did not increase the risk of significant cardiac morbidity, for the majority of cardiac surgical patients. (Further details of these studies are provided in Tables 1, 2 and 3 in Appendix A).

The drive for cost effective health care in the last two decades of the twentieth century prompted a number of studies. The majority of these are observational, before and after studies (grade C, (Phillips et al., 2001) and they have also reported that early extubation did not appear to result in greater incidence of cardiac morbidity or mortality.

In the UK, Chong and colleagues reported on their findings when setting up a cardiac surgical recovery area (CSRA) where patients could be managed using a rapid extubation protocol. Their papers report on findings on similar groups of patients before and after the changes in management (Chong et al., 1993 and Westaby et al., 1993). Although these

studies are not grade A evidence (Phillips et al., 2001), they have been influential, as they have been frequently cited in subsequent studies.

Chong et al. (1992) and Westaby et al., (1993) collected prospective data from patients undergoing coronary artery bypass grafts (CABG), or heart valve surgery or combinations of CABG and valve surgery. They found that over 90% of patients could be treated in the CSRA, i.e. could be successfully extubated early reducing the requirement for Intensive Care Unit (ICU) beds. Some patients were electively admitted to the ICU, because of the severity of their preoperative condition (those with severe multi-organ dysfunction, severe chronic respiratory disease or requiring prolonged cardiopulmonary bypass during surgery). Some patients were admitted to the ICU (2.25%) because they required prolonged postoperative respiratory and/or inotropic support (drugs to support the heart). One of the papers (Chong et al., 1993) compares the prospective findings with a retrospective control group of consecutive patients admitted for the same cardiac surgical procedures in the two months prior to the change in management. The surgical techniques and cardiopulmonary bypass (CPB) were the same for both groups. The new management group had a different anaesthetic protocol using a fast acting anaesthetic (propofol), which has a short half-life (i.e. its effects wear off rapidly once its administration has been discontinued), once CPB had started. The conventionally managed group had an anaesthetic that incorporated fentanyl (an opiate) and midazolam (a sedative agent whose effects wear off much more slowly compared to propofol). The authors reported that there was no higher incidence of morbidity or mortality under the new management regimen compared with the conventionally managed group.

In their review of early extubation Hickey and Cason, (1995) looked at 14 studies between 1974 and 1994. They reported that all the studies found that morbidity and mortality were

not affected by early extubation, and it was therefore safe for at least 70% to 80% of cardiac surgical patients. The other 20 to 30% were usually considered high-risk patients and, therefore, did not meet inclusion criteria for the studies. The authors of this review note that there were only two small, randomised controlled trials that reported no increased cardiac morbidity for patients extubated early. They also comment that other studies that were methodologically weaker (i.e. they did not have prospective control groups), but included a larger sample of patients, also indicated no increased cardiac morbidity. Hickey and Cason (1995) concluded that early extubation did not increase morbidity, for selected patients (i.e. low risk patients), but that the question of whether postoperative ischaemia is increased by early extubation and whether early postoperative myocardial ischaemia predicts clinically significant outcomes, such as myocardial infarction (MI) remained unresolved.

Since 1994, a number of observational studies has been published. Again they all appear to confirm the safety of early extubation, with no increase in cardiac morbidity or mortality rates. These studies mostly report a change in management to early extubation for adult cardiac surgical patients (see Tables 1, 2 and 3 in Appendix A). The majority used historical controls or retrospective data (Engleman et al., 1994, Coe, 1995, Gross, 1995, Higgins, 1995, Marquez et al., 1995, Edwards and Hess, 1996, Higgins et al., 1996, Jesurum et al., 1996, Riddle et al., 1996, London et al., 1997, Quigley and Reitknecht, 1997, Berdat et al., 1998, London et al., 1998, Hwang et al., 1999, Jacovone et al., 1999 and Reis et al., 2002); for some it is not clear what sort of control group was used (Kozlov et al., 1995); and some present audits of practice (Massey and Meggit, 1994, Howard, 1995 and Gale and Curry, 1999) or have no control group (Kaplan et al., 2002).

Although the number of centres reporting positive experiences of implementing early extubation seems to be a significant indication that the practice has been widely adopted, the evidence these studies provide for the safety of early extubation is limited. There are differences in anaesthetic technique, extubation criteria and patient populations (e.g. some include all types of cardiac surgery, some just CABG surgery and some include only low risk patients others include medium and/or high risk patients too). This makes direct comparisons between studies extremely difficult. The use of historical control groups is a significant methodological weakness because of the lack of control for the influence of confounding variables. There may also be some potential for publication bias in this evidence base. It is possible that only centres with successful experiences of implementing early extubation have published their results. It is possible that there may be centres that were unsuccessful or had negative experiences with early extubation that may not have published any findings.

Interest in very early extubation (either immediately after surgery or within 4 hours) has been discussed more recently. For example, Konstantakos and Lee (2000) in their retrospective matched cohort study, suggested that extubation within 4 hours, compared to within 8 hours, may be beneficial and warranted further investigation. There is further discussion of the effect of immediate and very early extubation on lung function in section 2.3 Respiratory Complications.

Further evidence of the safety of early extubation comes from Ovrum et al. (2000). They report on the results of applying early extubation, as part of a rapid recovery protocol, to their coronary artery bypass patients over 10 years. Although this is a retrospective review, it includes 5,658 patients and covers a ten-year period at one institution in Norway. The authors note that their patient population is selected, as some more high-risk patients

are operated on at a nearby institution. They report that 2.53% of their patients had a Myocardial Infarction (MI), but noted that this sub group of patients were treated similarly to the whole population with a median extubation time of 1.6 hours (range 0 - 312 hours). Of these 143 patients who had an MI, 134 survived (94%). The authors' stated that, neither this (MI), nor any other major complications could be associated with early extubation. Although they did not collect data by continuous monitoring of myocardial ischaemia, they felt that the low incidence of MI and reintubation due to cardiorespiratory decompensation (0.46%) and hospital mortality rate of 0.41% indicated that early extubation was a feasible and safe practice.

2.2.1b. The contribution of randomised controlled trials to the evidence base for the impact of early extubation on cardiac complications

When studying the safety and efficacy of a medical intervention, prospective randomised controlled trials (RCTs), are considered to produce more robust evidence for clinical practices (grade A evidence (Phillips et al., 2001), than observational studies, e.g. studies with retrospective control groups (Grimshaw et al., 2001b). The methodology used in RCTs is considered to provide the best control for confounding variables in studies of medical interventions. There are some RCTs in the early extubation literature, all of which contribute evidence for the safety of early extubation for coronary artery bypass patients.

Five randomised controlled trials conducted between 1980 and 1998 (Quasha et al., 1980, Cheng et al., 1996a, Reyes et al., 1997, Berry et al., 1998, Silbert et al., 1998) investigated the impact of early extubation on various cardiac outcomes. All five studies considered the incidence of myocardial infarction (MI). None found a significant difference in the risk of MI between the patients extubated early compared with those extubated conventionally.

Cheng et al. (1996a), Berry et al. (1998) and Silbert et al. (1998) reported on the level of cardiac enzymes (creatinine kinase MB (CKMB), which are released following damage to myocardial muscle. These levels are often used to indicate damage caused by myocardial ischaemia or, in particular, myocardial infarction, however cardiac surgery itself often results in some release of these enzymes. The usefulness of this measure can therefore be debated but significantly different levels in either group of patients could indicate an increased risk of myocardial ischaemia. Cheng et al. (1996a) and Berry et al. (1998) found no significant differences in the levels of CKMB between the early or conventionally extubated groups. Silbert et al. (1998) found significantly lower CKMB levels in the early extubation group compared with the conventional extubation group ($p < 0.02$), although the authors comment that the implications of this finding are unclear.

Myocardial ischaemia was measured using various measurements by investigators.

Myocardial ischaemia is an indication of reduced blood flow to the myocardium, but its role in determining or predicting the incidence of long term complications or permanent damage such as MI is not clear.

Berry et al. (1998) reported no differences in the incidence of myocardial ischaemia and Reyes et al. (1997) reported no differences in the rates of angina (the pain caused by myocardial ischaemia) between patients extubated early compared with those extubated using conventional practice. Cheng et al. (1996a) and Berry et al. (1998) both reported that the levels of ischaemic burden were not significantly different between the early and conventionally extubated patients. Berry et al. (1998) also used maximal ST-segment deviation and area under the ST deviation-time curve (integral of ST deviation and time) as measurements to detect ischaemia and found no significant differences between the two groups. The PQRS complex is a graphical representation of electrical activity during a

heartbeat commonly shown on an electrocardiogram (ECG). The ST segment is part of this complex. ST deviation is a change on the ECG that occurs with myocardial ischaemia. The length of time such deviations last can be an indication of the severity of any damage caused by such ischaemic episodes.

The patients' stress response to surgery and early extubation compared with surgery and conventional extubation were compared by Quasha et al. (1980) and Cheng et al. (1996a). Quasha et al. (1980) used plasma norepinephrine levels as a measurement of stress. Cheng et al. (1996a) also used plasma catecholamine levels, which include norepinephrine, to measure stress. Neither study found significant differences between the study and control groups.

Reyes et al (1997) report on a number of other cardiac complications. These were dysrhythmias (irregular heart beats), heart block (block in the electrical pathway which causes the heart to beat), hypertension (high blood pressure), pulmonary oedema (fluid on the lungs caused by heart not working efficiently) and low output syndrome (significantly reduced working of the heart causing not enough blood to be pumped around the body). There was no significant difference in the incidences of these complications between the two study groups.

These randomised controlled trials differed in their sample sizes, study populations, and early extubation and anaesthetic protocols as well as in some of the measurements of cardiac morbidity discussed above. Quasha et al. (1980) used a sample of 38 (18 randomised to the early extubation and 20 to the conventional extubation groups) CABG patients. Cheng et al's (1996a) sample was 120 (60 early and 60 late extubation) CABG patients. Berry et al. (1998) used a sample of 85 CABG patients randomised to either the

early extubation or late extubation group. Silbert et al. (1998) also studied CABG patients, randomising 100 patients to either the study or control groups. Reyes et al's study (1997) of 404 (201 early extubation and 203 conventional extubation) patients differed because it included all types of cardiac surgery (i.e. not only CABG patients, but also heart valve surgery or combination of CABG and valve surgery patients). The extubation protocol was significantly different to the other RCTs discussed in this section because patients were not considered for early extubation until 7 hours after surgery. The other studies' protocols considered patients for early extubation as soon as they were stable after surgery and define early extubation within 6 to 8 or 10 hours following surgery. Comparisons between Reyes et al's (1997) study and the others need to be made with caution because of this difference. Reyes et al's (1997) definition of early extubation also meant that all the patients in their study were sedated and ventilated during the first few postoperative hours when the incidence of ischaemia has been thought to be the greatest (Mangano et al., 1992).

The sample sizes, of the RCTs of early extubation discussed in this section, vary from 30 to 404. Usually larger samples are considered to give more accurate results (Pagano, 1990), so Reyes et al. (1997), with a sample of 404 patients, could be considered to provide more accurate evidence, but as discussed above there are methodological differences in Reyes et al. study that mean comparisons with the other RCTs should be made with caution. In particular the fact that early extubation was not considered until 7 hours postoperatively, which would have been considered conventional extubation in other studies (e.g. Cheng et al., 1996a). The rigour of a RCT is increased by sample sizes determined by a power calculation, which enables clinically significant outcomes to be detected. None of the studies reported that its sample size was determined by a power calculation.

These randomised controlled trials contribute the strongest available evidence (grade A or B (Phillips et al., 2001) that early extubation does not increase the incidence of cardiac morbidity for coronary artery bypass graft patients (CABG). However there are some limitations to consider. Only Reyes et al's study (1997) included heart valve surgery, so the results of the other four studies cannot be generalised to this group of cardiac surgical patients. It is not clear what the power of the sample sizes used were to detect statistically significant differences between the study and the control groups. There were some differences in the outcome measures used. Each of these studies was conducted at only one site, and although randomised it is possible that there were differences between the patient population in each study compared to the cardiac surgery patient population as a whole. The fact that evidence is replicated has some significance, but a multi-centre randomised controlled study or meta-analysis of results from different studies, if comparable, would provide even a stronger evidence base. A meta-analysis could provide a way of weighting the study results according to factors such as sample size and could test the significance of differences in study methodologies on the outcomes.

2.2.1c. Physiological Studies

Some studies have looked at the physiological effects of extubation on the myocardium (heart muscle). These studies aim to assess whether extubation creates additional stress on the myocardium, which could result in morbid events. Paulissian et al.(1991) looked at haemodynamic effects of extubation in coronary artery bypass graft patients and the effects of intravenous lidocaine (lignocaine), which had been found to reduce increases in heart rate and blood pressure in other types of surgery. Paulissian had two groups of patients, one received lidocaine (n=12) and the other had a placebo (n=13). They found that the haemodynamic responses were less pronounced than the previous work on other surgical

patients and that the lidocaine had no significant effects on patients' responses. They looked at heart rate, mean arterial blood pressure, cardiac dysrhythmias, electrocardiograph changes and CPK isoenzyme levels to indicate myocardial ischaemia. Although this study is a small physiological study (grade D (Phillips et al., 2001)), it adds some evidence of the effects of extubation on cardiac performance. However, all patients were extubated the morning following surgery (i.e. conventional extubation) so there is no comparison data with patients extubated earlier postoperatively.

Gall et al (1988) found that endotracheal extubation actually improved cardiac performance following uncomplicated cardiac surgery. Left ventricular function improved because of increased preload (left ventricular filling improved, due to a fall in intrapleural pressure after extubation). Their conclusions were from a detailed study of cardiac physiology of seven elective coronary artery bypass surgery patients (grade D evidence (Phillips et al., 2001)). They concluded that early extubation meant that patients with uncomplicated cardiac surgery could benefit from improved cardiac performance at an earlier stage postoperatively if they were extubated early.

2.2.1d. Summary of the evidence base for the effect of early extubation on cardiac outcomes

All the studies, observational, randomised controlled trials and physiological, discussed above have indicated that early extubation does not appear to increase the risk of cardiac complications for cardiac surgical patients. There may even be some benefit from improved cardiac function at an earlier stage in the postoperative period, for patients who are extubated early. The evidence, however, is not strong. The majority of studies were poorly controlled observational studies, grade C (Phillips et al., 2001), so the size of the effects of early extubation on the outcome measures might be exaggerated (Grimshaw et

al., 2001b). There are a number of randomised controlled trials, which could be considered to provide grade A/B evidence (Phillips et al., 2001). These trials vary in several aspects, such as sample size, outcome measures and definition of early extubation. They also lack power calculations to ensure adequate sample sizes to detect clinically significant outcomes. Although they all indicate the safety of early extubation, conclusions need to be cautious because they are limited by these methodological differences and weaknesses. A systematic review of randomised controlled trials would provide a stronger evidence base for the effects on cardiac morbidity and mortality of early extubation for adult cardiac surgical patients and would help identify further areas for research.

2.2.2 Respiratory Complications

Respiratory insufficiency is a consequence of cardiac surgery, however, the question as to whether early extubation increases the risk of respiratory complications has been another area of concern. Reintubation rate (the number of patients having to be put back on the mechanical ventilator because they were not able to adequately maintain their own ventilation following extubation) is a key outcome measure. This is because the decision to extubate a patient involves assessing the patient's ability to maintain adequate self-ventilation. The need for reintubation can be a direct result of a patient being extubated too early, although other factors can also be the cause of reintubation; e.g. the need for re-operation because of postoperative bleeding, or a cardiac arrest. Other respiratory complications, such as chest infections, intrapulmonary shunt (blood not being fully oxygenated in the lungs because areas of the lungs have collapsed), atelectasis (areas of collapsed lung) are harder to link directly to extubation because they are known complications of cardiac surgery. These variables have, however, been investigated because, if early extubation is safe compared with conventional extubation, the incidence of these variables should not be increased by early extubation.

Many of the studies that looked at the incidence of cardiac complication have also investigated respiratory variables to assess the safety of early extubation. Some other studies have focused specifically on respiratory outcomes. The same comments regarding methodology apply to the respiratory outcomes as to the cardiac ones, with randomised controlled trials providing stronger evidence (grades A or B (Phillips et al., 2001) than observational studies (generally grade C (Phillips et al., 2001)).

2.2.2a. The contribution of observational studies to the evidence base for the effect of early extubation on respiratory outcomes

The early studies from the 1970s that investigated early extubation not only considered the effects of early extubation on cardiovascular outcomes, but also the effects on respiratory outcomes. These studies (Klineberg et al., 1977 and Prakash et al., 1977) reported that early extubation did not appear to cause significant differences in respiratory outcomes. Klineberg et al (1977) found that 62.5% of patients could be extubated within 5 hours of surgery and 71% were extubated by 10 hours. None of the patients studied required reintubation. Earlier extubation was also associated with shorter intensive care unit (ICU) and hospital length of stays (for details see Table 3 in Appendix A).

Prakash et al. (1977) reported that 86% of patients were extubated within 3 hours. In contrast to Klineberg et al's (1977) reintubation rates, Prakash et al. (1977), in their study of 142 patients extubated early, found that of the 123 patients extubated within 3 hours, 5 (4%) required reintubation. This study did not have a control group for comparison of reintubation rates. It is, therefore, not possible to say whether a reintubation rate of 4% in this group of patients is significant. Prakash et al. (1977) also measured pulmonary gas

exchange and levels of oxygen (PaO_2) and carbon dioxide (PaCO_2) in the blood, concluding that early extubation was safe, based on these measurements.

Foster et al (1984), in their observational study of 63 CABG patients, using prospectively collected data for the study group and a historical control group, found that only 38% of the early extubation group were extubated within 8 hours. This contrasts with Prakash et al's (1977) finding that 86% of patients could be extubated within 3 hours and also with Klineberg et al's (1977) finding that 62.5% of patients could be extubated within 5 hours. Foster et al. (1984) suggested that a possible reason for the longer times to extubation was the use of high dose narcotic anaesthesia. It is not possible to comment on the significance of these comparisons, because the studies use different methodologies, including different anaesthetic techniques and where a control group is used, it is historical. These differences mean the results of the individual studies could be strongly affected by confounding variables and each study is not exactly comparable with the others.

A number of other observational studies and audits considered various respiratory outcomes for early extubation (Chong et al., 1993, Westaby et al., 1993, Engleman et al., 1994, Massey and Meggit, 1994, Gross, 1995, Howard, 1995, Coe, 1995, Higgins, 1995, Kozlov et al., 1995, Marquez et al., 1995, Edwards and Hess, 1996, Jesurum et al., 1996, Riddle et al., 1996, London et al., 1997, Quigley and Reitknecht, 1997, Berdat et al., 1998, Jacovone et al., 1999, Hwang et al., 1999, Gale and Curry, 1999, Ovrum et al., 2000, Kaplan et al., 2002, and Reis et al., 2002). Many of these studies demonstrate significantly shorter ventilation times and low reintubation rates for patients managed with an early extubation protocol. Earlier resumption of self-ventilation means patients can commence their postoperative rehabilitation earlier and may be discharged from hospital earlier. Shorter intensive care and hospital length of stays are also reported in many of these

studies. Table 3 in appendix A provides a summary of the results for respiratory and length of stay outcomes from these observational studies. It should be used in conjunction with Table 1 in appendix A, which gives methodological details of the studies.

Table 2.2.2a provides a comparison of the results of several of the observational studies discussed above. The following outcomes are presented for comparison: reintubation rate, mean extubation time, median extubation time, mortality rate, atelectasis (areas of collapsed lung) and the percentage of patients successfully extubated.

Reintubation rates vary from 0% (Klineberg et al., 1977, Foster et al., 1984, Higgins, 1995 and Marquez et al., 1995) to 4% (Prakash et al., 1977) of patients extubated early. Those studies with control groups appear to indicate that there are no significant differences between reintubation rates for study and control groups.

Mean extubation times for the early extubation groups range from 7 hours (Johnson et al., 1997) to 10.9 hours (Higgins, 1995). Median extubation times range from 1.5 hours (Ovrum et al., 2000) to 2 hours (Chong et al., 1993). Some authors present median rather than mean times because the mean times are more affected by extreme outlying values for the variable. Patients who are not extubated early can easily be ventilated for 24, 48 or more hours, and even one such patient can increase the mean extubation time. Some authors and clinicians may have regarded the median as a more reliable statistic for evaluating the effect of early extubation on ventilation times and chose to present this statistic in their paper. Another reason for the differences in the mean and median results may be due to the different designs of the studies. Two studies reported mortality rates, 0.41% (Ovrum et al., 2000) and 1.4% (Westaby et al., 1993).

Johnson et al. (1997) used an atelectasis score in their study, which indicated a significantly higher score (i.e. worse atelectasis) for the conventional extubation group on the day of extubation. The percentage of patients successfully extubated varied. Ovrum et al. (2000) and Klineberg et al. (1977) reported that 99% and 62.5% of patients respectively were extubated within 5 hours of surgery. Prakash et al. (1977) reported that 87% of their patients were extubated within 3 hours. In contrast Foster et al. (1984) found only 38% of their patients could be extubated within 8 hours of surgery.

The observational studies in Table 2.2.2a and Table 3 in appendix A seem to indicate that early extubation does not increase respiratory morbidity for cardiac surgical patients. The evidence should be treated with some caution because of the lack of prospective, random samples. This could mean that confounding variables may account for the results. Only research designs that use samples randomly selected from a population are considered to enable generalisations to be made from the sample, to the population. A randomised controlled trial (RCT) is one such design. As the observational studies do not meet this criterion, their findings cannot be generalised to the population of cardiac surgical patients.

Table 2.2.2a Observational Studies – Respiratory Outcomes

Study	Methodology	Sample size	Reintubation Rate	Mean (SD) extubation Time	Median (range) Extubation time	Mortality Rate
Klineberg et al. (1977)	Observational study. Retrospective review of patient records. 2 study groups: early and conventional	Conventional extubation n = 31 Early extubation n = 72	0 0			
Prakash et al. (1977)	Observational study of consecutive patients.	Early = 142	5/123 (4%) of those extubated within 3 hours were reintubated: respiratory distress (1), re-operation for postoperative bleeding (2) MI (1) IABP needed preoperatively following a perforated septum following an MI (1).			
Foster et al. (1984)	Prospective observational study	Conventional extubation n = 27 Early extubation n=36	Not given 0	18.2 hours 10.8 hours		

Study	Methodology	Sample size	Reintubation Rate	Mean (SD) extubation Time	Median (range) Extubation time	Mortality Rate
Chong et al. (1992)	Observational	245 consecutive patients all considered for early extubation	1.8% (1 patient for respiratory apnoea (patient not breathing) and 4 for re-operation for bleeding)		2 hours	
Chong et al. (1993)	Observational with historical control group	Conventional extubation n = 80 Early extubation n=223	0 2% (5 patients)		7 hours (0-18) 2 hours (0-18)	
Westaby et al. (1993)	Observational	1000 consecutive patients all considered for early extubation				1.4%

Study	Methodology	Sample size	Reintubation Rate	Mean (SD) extubation Time	Median (range) Extubation time	Mortality Rate
Higgins (1995)	Observational. Comparison of an early extubation protocol with historical control group of patients extubated early before the formal protocol introduced	Early extubation pre protocol n = 579	0	14.4 hours		0
		Early extubation post protocol n= 104	0	10.9 hours		0
Marquez et al. (1995)	Observational with historical control group	Conventional extubation Early extubation	 0	 24 hours 10 hours		

Study	Methodology	Sample size	Reintubation Rate	Mean (SD) extubation Time	Median (range) Extubation time	Mortality Rate
Johnson et al. (1997)	Observational with matched historical control group	Conventional extubation n =112 Early extubation n =31		22 hours 7 hours	(12-48) (3-12)	
Ovrum et al. (2000)	Observational. Review of 10 years data on early extubation	5,658 patients over 10 years all managed with an early extubation protocol	1.1% (mainly for re-operation for bleeding or cardiopulmonary decompensation)		1.5 hours (0-320)	0.41%

Table 2.2.2a continued

Study	Atelectasis	Percentage of patients successfully extubated	Comments
Klineberg et al. (1977)		Early group: 62.5% were extubated within 5 h, 71% by 10 h, 85% by 20 h and 91% by 25h Conventional group: 3.2% by 5 h, 6.4% by 10 h, 16.2% by 15h, 61.2% by 20h and 77.2% by 25 h.	
Prakash et al. (1977)		123 out of 142 patients were extubated within 3 hours of surgery.	Pulmonary gas exchange variables showed no significant changes over 36 hours postoperatively
Foster et al. (1984)		38% of early extubation patients extubated within 8 hours	Six of the early group were discontinued from the early extubation protocol: 3 for "prolonged lethargy", one for hypotension (low blood pressure) and one had a problem with the endotracheal tube. The authors comment that their use of high doses narcotic analgesia without reversal after surgery, may account for the longer times to extubation in their early group compared to other studies.

Study	Atelectasis	Percentage of patients successfully extubated	Comments
Westaby et al. (1993)		1% failure in the early extubation policy because of complications, including chronic lung disease causing poor respiratory function, induction aspiration, perioperative MI, left ventricular failure (LVF).	
Marquez et al. (1995)			<p>Patients in the early extubation group were not considered for weaning and extubation until 3 to 5 hours post surgery, which is different from several other studies and reports, which considered patients for weaning and extubation immediately after surgery.</p> <p>These sorts of differences in the management protocols of various studies contribute difficulty to direct comparison of results.</p>

Study	Atelectasis	Percentage of patients successfully extubated	Comments
Johnson et al. (1997)	As expected there was an increase for both groups in atelectasis score compared with preoperative score, but this score was significantly higher on the day of extubation, in the conventional extubation group compared with the early extubation group.		They also found a significantly decreased lung function (measured on spirometry) in the late extubation group (FEV ₁ /FVC ratio) on postoperative day 5. The authors found a significantly greater fluid balance until extubation in the conventional extubation group and suggest that this could have caused greater airway oedema or that increased airway obstruction limitation possibly caused by a higher dose of sufentanil (an opiate) used for the conventional group may have been the cause of the results in respiratory function and atelectasis.

Study	Atelectasis	Percentage of patients successfully extubated	Comments
Ovrum et al., 2000		99% of patients extubated within 5 hours	

Direct comparisons between the observational studies are also difficult because of the use of different methodologies, such as type of control group used or not control group, differences in outcome measures and different management protocols. For example, patients in the early extubation group in Marquez et al's study (1995) were not considered for weaning and extubation until 3 to 5 hours post surgery, which is different from several other studies and reports (e.g. Chong et al., 1993 and Ovrum et al., 2000), which considered patients for weaning and extubation immediately after surgery. Low reintubation rates were, however, reported in most studies from 0 to 1.8% providing some evidence (grade C/D (Phillips et al., 2001) that appears to support the safety of early extubation.

2.2.2b The contribution of randomised controlled trials to the evidence base for the effects of early extubation on respiratory outcomes

The randomised controlled trials, discussed earlier in the cardiac morbidity section, also provide evidence for the effect of early extubation on respiratory morbidity. This evidence is stronger (grade A/B (Phillips et al., 2001) than that of the observational studies presented above (grade C/D (Phillips et al., 2001). The studies investigated various measures of respiratory function and present their results in different ways. Not all respiratory measures were used by all the studies, making comparisons difficult. The lack of replication means some of the results need to be treated with caution until further research confirms or refutes the findings.

Respiratory outcomes investigated include: percentage of patients extubated early (according to the study's definition of early, i.e. within 8 hours for Quasha et al. (1980) and within 6 hours for Cheng et al. (1996a)); intrapulmonary shunt (Quasha et al., 1980 and Cheng et al., 1996a); mean or median extubation times (Quasha et al., 1980, Reyes et al.,

1997), venous admixture (Quasha et al., 1980); incidence of pneumonia (Quasha et al., 1980); lung infection causing respiratory failure (Reyes et al., 1997); lobar collapse or atelectasis (Quasha et al., 1980, Cheng et al., 1996a); apnoea (Cheng et al., 1996a); respiratory pattern (Cheng et al., 1996a); arterial blood gas levels at various time points (Cheng et al., 1996a); alveolar - arterial oxygen gradient oxygen consumption (Cheng et al., 1996a).

Quasha et al. (1980) reported that 2 of the patients in their early extubation group (n=18) failed to meet the arbitrary cut off point of 8 hours. One of these was reintubated for respiratory failure. Intrapulmonary shunts were not significantly different at the end of anaesthesia between the study groups. The average time to extubation of the early extubation group (excluding the 2 patients who were not extubated within the 8 hour period) was 2.2 hours compared with 18 hours for the conventional group. The authors report no significant differences between the groups in terms of the respiratory outcomes studied (intrapulmonary shunt, venous admixture, pneumonia, lobar collapse). The findings of this study need to be treated with caution because of the small sample size.

In Cheng et al.'s randomised controlled trial (1996a) the following respiratory outcomes were studied: apnoea and respiratory pattern, arterial blood gases, alveolar-arterial oxygen gradient, intrapulmonary shunt and oxygen consumption, atelectasis. Differences between the two groups were found only in a significantly lower intrapulmonary shunt at 4 hours post extubation in the early extubation group and that the early group also had a consistently lower minute ventilation and mainly abdominal breathing after extubation compared with the conventional extubation group. This second finding did not appear to have a clinically significant effect on the other respiratory outcomes, according to the authors. The reduction in intrapulmonary shunt is a positive outcome and appears to

contrast with Quasha et al's (1980) findings that there was no difference between the intrapulmonary shunt in the study and control groups. The measurements for intrapulmonary shunt however, were taken at different times in the two studies (Quasha et al. 1980 at the end of anaesthesia and Cheng et al. 1996a at four hours after surgery) and so are not directly comparable. Cheng et al. (1996a), when discussing this positive outcome (improved intrapulmonary shunt), also comment that atelectasis (which can contribute to intrapulmonary shunting) may well be increased in patients who are ventilated longer than 24 hours post surgery.

Early extubation was defined as within 6 hours in Cheng et al's study (1996a) and 85% of patients in this group were extubated within 6 hours. The conventional extubation group were assessed for extubation at 7 am the morning following surgery and 85% of these patients were extubated within 22 hours after surgery. The reasons for why patients failed the extubation criteria within the defined time periods were similar for both the conventional and early extubation groups. This study indicates that about 85% of patients could be extubated within 6 hours of surgery and could possibly benefit from improved respiratory function.

Reyes et al. (1997) considered their patients for early extubation at 6 hours post surgery, which makes the findings difficult to compare with Quasha et al's (1980) and Cheng et al's (1996a) studies because they defined early extubation as within 8 and 6 hours respectively. In Reyes study (1997) the median time to extubation was 10 hours (range 1-679) for the early group and 21 (range 1-1,233) for the conventional group. 60.2 % of patients were extubated within 11 hours in the early extubation group. There was no significant difference in reintubation rates between the study groups (6.5% in the early group and 3.5% in the conventional group). However, there was a significance in the incidence of

reintubation and need for mechanical ventilation after 48 hours. When complications were analysed separately, the early group had a higher incidence. The reasons for reintubation were cardiogenic shock (2 patients), somnolence, hypercapnia (high carbon dioxide levels in the blood), and hypoxaemia (low oxygen levels in the blood) (1 patient), lung infection causing respiratory failure (2 patients), acute cerebral accident (stroke) (1 patient), and perforated duodenal ulcer (1 patient). In the conventional group two patients were reintubated, one for acute cerebral accident and one for severe heart failure due to endocarditis (infection of the inside lining of the heart). The authors comment that, in spite of the higher re-intubation rate in the study group, it is unlikely that early extubation had any role in these patients being reintubated. There was no significant difference in the mortality rates between the two groups.

These randomised controlled trials contribute evidence at levels A/B (Phillips et al., 2001) for the safety of early extubation. They indicate that there is probably no increased risk of respiratory complications for early extubation compared to conventional extubation for cardiac surgical patients. There may also be some evidence that patients who are extubated early could benefit from improved respiratory function. The improvement in intrapulmonary shunt that could contribute to improved respiratory function, was found in only one study (Cheng et al., 1996a) and needs to be confirmed or refuted by further research.

As with the evidence they provide for incidence of cardiac complications, the methodologies of these RCTs mean there are some limitations to their findings. These trials vary in several aspects, such as sample size, outcome measures and definition of early extubation. They also do not report power calculations to ensure adequate sample sizes to detect clinically significant outcomes. Although they all indicate the safety of early

extubation, conclusions need to be cautious because they are limited by these methodological differences and weaknesses. A multicentre RCT or systematic review of randomised controlled trials, including a meta-analysis, would provide a stronger evidence base for the effects on respiratory morbidity of early extubation for adult cardiac surgical patients and the systematic review would help identify further areas for research.

2.2.2c Very early or immediate extubation and its affects on respiratory outcomes

As early extubation has become more widely adopted during the 1990s, some researchers have begun to question if there is a limit to how early patients can be safely extubated. This debate was briefly introduced in the cardiac outcomes section 2.2.1 in the discussion of Konstantakos and Lee's (2000) paper. Some researchers have begun to look specifically at the effect of immediate or very early extubation on lung function.

Mcguire et al. (2000) conducted a prospective observational study on 100 elective cardiac patients, excluding those with chronic lung disease, pulmonary venous congestion or likely to require CPB for longer than 2.5 hours because of complex surgical procedures. They looked at the effect of postoperative ventilation time on lung function. Three groups were compared: group I (n=29) patients were extubated prior to leaving the operating room, group II (n=37) within 8 hours and group III (n=28) after 8 hours. These groups were demographically similar and the variables investigated were; oxygen saturation on air, spirometry and chest x-rays. Preoperative values were compared with those measured on postoperative days 2, 3 and 4. Although lung function was significantly reduced following surgery (as expected), there were no significant differences between the three groups. The authors concluded that immediate extubation did not appear to worsen lung function compared to early and conventional extubation. Although this study was not a randomized control trial and used a small sample, it is useful as it specifically looked at lung function

outcomes and adds to the evidence that the time of extubation does not appear to increase the risk of respiratory complications for patients following cardiac surgery. Further research using a high quality methodology, such as an RCT using a power calculation to determine the sample size, is needed to confirm or refute these findings.

2.2.2d Summary for the evidence base for the effect of early extubation on respiratory outcomes

Both the randomised controlled trials and observational studies discussed in this section of the literature review appear to report positive outcomes for early extubation. The practice not only appears as safe as conventional extubation, but there may be some evidence for early extubation improving respiratory function. The evidence seems more variable than that for the cardiac outcomes discussed in section 2.2.1, because there does not seem to be a consensus of what the best measures of respiratory function are (different studies use a variety of outcome measures, many of which are not replicated in other studies). The clinical significance of some of the outcomes is also not clear and this may contribute to the variety used.

As with the discussion of cardiac outcomes, there are limitations to the evidence base for respiratory outcomes because of methodological weaknesses in the study designs. The majority of studies were poorly controlled observational studies, grade C (Phillips et al., 2001), so the size of the effects of early extubation on the outcome measures may be exaggerated. There are a number of randomised controlled trials, which could be considered to provide grade A or B evidence (Phillips et al., 2001). These trials vary in several aspects, such as sample size, outcome measures and definition of early extubation. They also lack power calculations to ensure adequate sample sizes to detect clinically significant outcomes. Although they all indicate the safety of early extubation, conclusions

need to be cautious because they are limited by these methodological differences and weaknesses. A multicentre RCT or systematic review of existing randomised controlled trials, including a meta-analysis, would provide a stronger evidence base for the effects on respiratory morbidity and mortality of early extubation for adult cardiac surgical patients and would help identify further areas for research.

2.2.3 Summary for the Literature on the Safety of Early Extubation

From the published literature, early extubation seems to be a safe practice because it does not appear to increase the risk of cardiac or respiratory morbidity or mortality when compared to the conventional practice of ventilating patients overnight following cardiac surgery. The evidence base does, however, have some limitations. The majority of studies are observational and use historical control groups. The use of historical control groups means that confounding variables are not well controlled and may influence the results and may mean the size of the effects of early extubation on the outcomes studied may be exaggerated (Anderson et al., 2004). Apart from the limitations in the conclusions that can be drawn from the results of these studies, the differences in the methodologies used make comparisons difficult (e.g. anaesthetic techniques, extubation criteria, patient populations).

The RCTs provide the strongest and most reliable evidence to date (grade A or B according to Phillips et al. (2001)). Generalisations from the RCT's sample to the population can be made. The evidence for the impact on early extubation on cardiac complications or outcomes is possibly stronger than that for the respiratory outcomes. This is because there was more replication of results in particular cardiac outcomes such as the incidence of MI, than there are for the respiratory outcomes studied.

As with the observational studies, differences between the RCTs, such as the definitions of early extubation, anaesthetics used and patient populations make direct comparisons difficult. Methodological weaknesses, in particular the small sample sizes and the lack of power calculations to determine samples large enough to detect clinically significant differences in the outcome measures, mean the results should be treated with some caution.

The evidence base for the safety of early extubation could be strengthened by further research, such as a multi-centre RCT or a meta-analysis of existing RCT data.

2.3 RISK FACTORS FOR PROLONGED VENTILATION AND REQUIREMENT FOR REINTUBATION AFTER CARDIAC SURGERY

With the interest in establishing the safety of early extubation for cardiac surgical patients, came an interest in identifying patients suitable for early extubation and identifying those at risk of requiring prolonged ventilation. Some studies have looked at preoperative risk factors and others at intraoperative and perioperative factors influencing ventilation times. Rady and Ryan (1999) attempted to identify pre-, intra- and postoperative variables that can predict the need for reintubation. The following Tables 2.3i and 2.3ii summarise the main findings of these studies.

The findings concerning preoperative variables seem inconclusive, with some studies finding some variables are significant predictors and others finding the same variables are not significant predictors. The majority of studies consist of retrospective reviews of

medical records and use univariate analysis followed by multivariate logistic regression analysis to identify significant predictive variables. Because of the retrospective data used, there is likely to be a lack of control of extraneous or confounding variables (e.g. surgical technique, anaesthetic technique, extubation criteria, measurement tools) within and between the studies. This makes comparisons difficult and may account for the variability of the results. The information provided in these studies does, however, make an interesting starting point for the discussion about the predictive value of variables. Two studies have used a prospective sample (Cheng et al., 1997) and (Doering et al., 1998) providing stronger evidence. Cheng et al. have gone on to develop a risk assessment score that they intended to test for reliability and validity (Wong et al., 1999).

Summary of Studies to Identify Predictive Variables for Prolonged Ventilation after Cardiac Surgery

Table 2.3i The Role of Preoperative Variables in Predicting Prolonged Ventilation

Study	Methods	Analysis	Statistically significant predictive preoperative Variables	Conclusions and comments
Tuman et al., (1992)	Development of a risk assessment score		Emergency surgery; type of surgical procedure (especially valve combined with CABG surgery); advanced age (the odds ratio for those aged 65-74 years was 1.36, increasing to 2.26 for those 75 and over); recent myocardial infarction, preoperative renal dysfunction, preoperative cerebrovascular disease, previous cardiac operation; pulmonary hypertension, congestive heart failure, female gender and severe left ventricular dysfunction.	Although useful for predicting patients at risk of postoperative complications, all the patients used to validate the assessment score were extubated with conventional management. No firm conclusions may be drawn about the effects of the management of early extubation patients on these variables, or whether this type of risk assessment is valid for patients managed differently.

Study	Methods	Analysis	Statistically significant predictive preoperative Variables	Conclusions and comments
Alexander and Cooper (1996)	Used a validated mortality risk score to identify patients suitable for a new early extubation protocol. A cohort of 153 consecutive CABG studied following early extubation protocol implementation and compared with retrospective data from a review of notes			<p>The authors report a 40% reduction in ventilation times for patients without complications, compared to the data collected before the protocol implementation. They also report reductions in average ventilation times of patients who had some postoperative complications.</p> <p>The authors concluded that low preoperative mortality risk was predictive of successful early extubation and therefore a useful tool in predicting patients least likely to have postoperative complications.</p>

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Habib et al., (1996)	Retrospective review of medical records of 507 CABG patients (47% required >8 hours ventilation and 3% > 24 hours ventilation)	Logistic and multivariate analysis	Increased age New York Heart Association functional class IV	

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Spivack et al., (1996)	Tested preoperative organ function variables (including cardiac and lung). Used a prospective cohort of 513 CABG patients in 1 centre to assess the predictive value of the variables for ventilation requirement of >48 hours.	Multiple regression analysis	Reduced LV ejection fraction	None of the respiratory variables were predictive. The authors concluded that only left ventricular ejection fraction was a good predictor of prolonged ventilation after CABG surgery. Although the data from this prospective observational study is helpful for CABG patients, they did not look at the predictive values for patients extubated early in less than 8 to 10 hours.

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Thompson, et al., (1997)	They reviewed the case notes of 139 cardiac surgical patients who required ventilation for 7 or more days postoperatively.		Urban residence Chronic obstructive pulmonary disease	

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Cheng et al. (1997)	Prospective data collected on 886 consecutive CABG patients studied. 25% of these were ventilated for > 10 hours	Univariate analysis (t-test and chi-square) followed by multiple logistic regression	Age: The odds ratios (OR) for the age groups studied were as follows: 60-69 OR = 1.67; 70-79 OR = 2.22 and 1.86 for those aged 80 and over. All the above groups were compared with patients under 60 years of age.	Although this was a prospective study, which provides stronger evidence than retrospective studies, data is only from one centre, making generalisations difficult. Wong et al (1999), give a fuller report of this study and the development and validation of a clinical risk score using the findings of this study.

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Bando et al., (1997)	Retrospective review of 568 CABG and/or valve operation records at 2 centres	Univariate analysis followed by multiple regression analysis	Priority of operation CCF Renal insufficiency Recent MI Previous operation	Intra operative cardiac function and postoperative complications have more influence on extubation times than preoperative variables. Preoperative lung function variables were not found to be significant predictors of ventilation time. The authors, therefore, question the value of preoperative lung function tests.

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Doering et al., (1998)	Data collected prospectively on a consecutive series of 116 CABG patients.	Univariate and logistic regression analysis	Older age	Prospective study, so findings are more reliable than retrospective studies. Older age was significantly associated with intubation for more than 6 hours. For every 1 year age increased the risk of being ventilated longer than 6 hours increased by 6.2%.

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Rady and Ryan (1999)	Retrospective review of 11,330 medical records to predict requirement for reintubation (not prolonged ventilation). 748 or 6.8% of these patients required reintubation. All patients were considered for early extubation.	Univariate analysis followed by multivariate logistic regression analysis	Age > 64 years Inpatient surgery Arterial vascular disease COPD Pulmonary hypertension Severe LV dysfunction Cardiac shock Haematocrit of < 34% High blood urea nitrogen Low serum albumin levels Low systemic oxygen delivery Redo operation	Most of the variables found to have predictive value for requirement for reintubation were poor preoperative cardiac, lung and renal function

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Walthall et al., (2001)	Retrospective review of medical records. Random sample of 100 records from 1 surgeon in 1 centre	Multivariate simultaneous linear regression	LV function	Although some attempts to reduce variability in this study, using one surgeon, randomly selecting notes for review, were made, it is still not possible to generalise the findings as it is a retrospective case review in one centre.

Table 2.3.ii The Role of in Intraoperative and Postoperative Variables Predicting Prolonged Ventilation

Study	Methods	Analysis	Statistically significant predictive intraoperative and postoperative variables	Conclusions and comments
Habib et al., (1996)	Retrospective review of medical records of 507 CABG patients (47% required >8 hours ventilation and 3% > 24 hours ventilation)	Logistic and multivariate analysis	Intraoperative fluid retention. This was affected by CPB time (longer CPB = greater fluid retention)	

Study	Methods	Analysis	Statistically significant predictive intraoperative and postoperative variables	Conclusions and comments
Thompson et al., (1997)	Reviewed the case notes of 139 cardiac surgical patients who required ventilation for 7 or more days postoperatively.		Prolonged operation and CPB time Intra operative cerebrovascular accident	Increased mortality rather than increased ventilation was associated with: Number of days requiring inotropes (drugs to support heart function) Sepsis Use of fresh frozen plasma to treat coagulopathy

Study	Methods	Analysis	Statistically significant predictive intraoperative and postoperative variables	Conclusions and comments
Cheng et al., (1997)	Prospective data collected on 886 consecutive CABG patients studied. 25% of these were ventilated for > 10 hours	Univariate analysis (t-test and chi-square) followed by multiple logistic regression	Inotrope use (odds ratio 1.86) IABP use (odds ratio 3.58) Atrial arrhythmias (odds ratio 1.85)	Although this was a prospective study, which provides stronger evidence than retrospective studies, data are only from one centre. A repeat of the study at other centres would strengthen the evidence base. Wong et al (1999), give a fuller report of this study and the development and validation of a clinical risk score using the findings of this study.

Study	Methods	Analysis	Statistically significant predictive intraoperative and postoperative variables	Conclusions and comments
Bando et al., (1997)	Retrospective review of 568 CABG and/or valve operation records at 2 centres	Univariate analysis followed by multiple regression analysis	Bleeding Reduced cardiac output (CO) Stroke Coma Level of CKMB released postoperatively	
Doering et al., (1998)	Data collected prospectively on a consecutive series of 116 CABG patients.	Univariate and logistic regression analysis	Early haemodynamic instability	Haemodynamic instability in the first 3 hours after surgery increased the risk of being ventilated for longer than 6 hours. Prospective data strengthens the findings.

Study	Methods	Analysis	Statistically significant predictive intraoperative and postoperative variables	Conclusions and comments
London et al., (1998)	Retrospective review of 304 consecutive CABG, valve, and CABG + valve patients	Univariate and logistic regression analysis	<p>Sufentanil dose</p> <p>Fentanyl dose</p> <p>Major inotrope use</p> <p>Platelet transfusion</p> <p>Use of arterial grafts</p> <p>Time of arrival on ICU</p>	<p>Prolonged ventilation defined as > 10 hours. The time of arrival on ICU was a factor specific to this unit. The staff caring for patients overnight were more reluctant to extubate patients due to the level of support available at night in the case of complications following extubation.</p> <p>The patients who were operated on at the end of the day, were therefore, likely to have longer ventilation times.</p> <p>The authors point out that the results need to be treated with caution as the data is retrospective and so cannot determine causal links.</p>

Study	Methods	Analysis	Statistically significant predictive preoperative variables	Conclusions and comments
Rady and Ryan (1999)	Retrospective review of 11,330 medical records to predict requirement for reintubation (not prolonged ventilation). 748 or 6.8% of these patients required reintubation	Univariate analysis followed by multivariate logistic regression analysis	Surgery involving the aorta Transfusion of ≥ 10 blood products CPB time of ≥ 120 minutes	

2.3.1 Preoperative Risk Factors

A number of the studies (Tuman et al., 1992, Habib et al., 1996, Spivack et al., 1996, and Walthall et al., 2001) found that variables that may cause poor cardiac function (e.g. congestive cardiac failure, recent myocardial infarction and, particularly, poor left ventricular function) were associated with longer ventilation times. In Rady and Ryan's study (1999) poor cardiac function was associated with the increased requirement for reintubation.

Serna et al. (1998) looked specifically at patients with poor left ventricular function because poor heart function constantly appears to be significant in longer recovery and ventilation times. They compared a consecutive group of 27 CABG patients with an ejection fraction of 30% or less (poor function) with a concurrent group of 27 patients with ejection fractions of 50% or more. They were also specifically assessing this "at risk" group's suitability for early extubation. All patients were managed on a care pathway that included early extubation. The two groups differed significantly on several variables: the poor ejection fraction group was more likely to have three vessel disease (more severe heart disease), congestive cardiac failure, renal insufficiency, longer cardiopulmonary bypass times, longer aortic cross clamp times, more distal anastomoses, and more requirement for intra-aortic balloon pump. Angina was more prevalent in the group with better left ventricular ejection fractions. These differences mean that the control and study groups were not particularly well matched and the results should be treated with caution. However, the variables that were different for the poor left ventricular function group may well be the cause of, or result in, poor heart function and so it is not surprising there is a higher incidence in this at risk group. The findings of the study showed that 52% of patients with low left ventricular ejection fractions were able to be extubated within 6 hours, compared to 96% of those with better ejection fractions. The authors suggest that

their data indicate that patients with low ejection fractions may be safely treated on accelerated care pathways (fast-track cardiac surgery), and this should be studied further.

Some of the studies (Tuman et al., 1992 and Thompson et al., 1997) have found that preoperative lung function variables and diseases associated with poor lung function (e.g. chronic pulmonary obstructive airways disease (COPD) and pulmonary hypertension) are associated with the need for longer ventilation times. Others have found the opposite (Spivack et al., 1996, Bando et al., 1997, Cheng et al., 1997, and Walthall et al., 2001). The evidence is again inconclusive, although it seems to suggest that poor preoperative lung function may not be significantly associated with the need for longer ventilation after cardiac surgery. Rady and Ryan (1999) did find a significant association between poor lung function and requirement for reintubation, but further research, using a stronger design is needed before this finding can be considered conclusive.

Increasing age is frequently associated with the requirement for prolonged ventilation in the studies discussed above. The incidence of morbidity is also higher among older people following cardiac surgery. Whether patients should be considered for early extubation on fast track care pathways has been debated. Older patients were specifically studied by (Rady et al., 1998) to identify variables that influence outcomes in the older cardiac surgical population. Lee, J H et al. (1998 and 1999) and Ott et al. (1997) also studied older patients to assess how suitable they are to follow fast track programmes, including early extubation.

Rady et al. (1998) conducted a study to identify perioperative factors influencing outcome in the older cardiac surgical patient (aged 75 years and over). They studied a comprehensive range of variables, in a consecutive series of older patients at their centre

and used univariate, multivariate and multiple logistic regression analysis to identify significant factors that could predict outcomes for this patient group. They found that factors such as the requirement for intra-aortic balloon pump support, severe heart disease, intraoperative blood loss, surgical re-exploration, long ischaemic times during surgery, global ischaemia, anaemia into the second postoperative day and metabolic dysfunction were predictors of poor outcomes, including longer ventilation times. These variables are also significant for predicting younger patients' outcomes, but the incidence of the significant preoperative variables is higher in older people. This is due to the effects of ageing, which may mean that the organs of the body have less reserve function to cope with the insult of major surgery. Rady et al. (1998) also found that, as with younger patients, morbidity for older patients was better predicted if preoperative and operative variables were combined when assessing risk.

Ott et al. (1997) studied 37 consecutive patients aged eighty and over who had CABG surgery using a rapid recovery protocol (fast track), following its successful use for patients aged seventy and over. Patients in this study, who required urgent or emergency surgery, had an elective intra-aortic balloon pump preoperatively, although this is not routine practice in many centres. The results were analysed comparing those patients who were discharged home within 10 days and those discharged at 10 days or more, to identify variables associated with longer recovery times. Although early extubation was part of the management of these patients, no results for extubation times were presented and the main outcome is hospital length of stay. The authors concluded that their fast track protocol was safe and effective for octogenarians because 71% were discharged in less than 10 days.

Lee, J H et al. (1998 and 1999) report on their study to assess the feasibility of fast track protocols, including early extubation, for older patients. The sample was a consecutive

group of 487 CABG patients whose operations were performed by one surgeon. Of these, 176 were aged 70 or over. This group was compared with the remaining 311 patients forming a cohort of younger patients. Although not a randomised trial, this study does offer some evidence for the safety of early extubation. The results are not generalisable because it does not use a random sample, but the study does compare outcomes for older patients with those of younger patients. The demographic characteristics of the two groups were not identical. There were proportionately more women in the older group, there was a significantly higher incidence of congestive cardiac failure, peripheral vascular disease, renal failure, previous stroke, cerebrovascular disease, carotid disease, impaired left ventricular function (defined as an ejection fraction of less than 40%) and lower body weight. These findings show that older people, certainly in this population, were more likely than younger patients to have factors associated with increased risk for surgery. Early extubation (within 8 hours) was one of the outcome measures reported on. It was achieved for 71% of the younger patients and 57% of the older group. Although the difference is significant between the two groups in terms of percentages successfully extubated early, more than half of the older patients were successfully extubated early. The authors conclude, however, that although age was an independent variable in predicting longer hospital length of stay, many of this cohort did well on the fast track protocol and that age alone should not be used to exclude patients from benefiting from fast track care. They conclude that fast track care, including early extubation, is safe for older patients.

2.3.2 Intraoperative and Postoperative Risk Factors

The evidence base for the predictive value of preoperative variables for the requirement for prolonged ventilation or reintubation after cardiac surgery is inconclusive. This, combined with clinical experience, has prompted researchers to investigate the role of intraoperative

and postoperative variables in longer ventilation times and the requirement for reintubation.

Table 2.3ii summarises these studies' findings.

Two studies found that prolonged cardiopulmonary bypass (CPB) appeared to increase ventilation times (Thompson et al., 1997 and Rady and Ryan, 1999). Rady et al, (1999) found that CPB times of 120 minutes or more were associated with longer ventilation times. Habib et al (1996) found that fluid retention increased ventilation times and commented that increased fluid retention was the result of prolonged CPB times.

Certain measures used to support the heart were also found to be predictive of prolonged ventilation. These were the use of inotropic drugs (Cheng et al., 1997 and London et al., 1998) and the use of an intra-aortic balloon pump (IABP) (Habib et al., 1996 and Cheng et al., 1997).

The use of blood products was also associated with longer ventilation times in three studies. Habib et al. (1996) et al report that blood transfusions were significantly predictive, Rady and Ryan (1999) found that transfusions of ten or more units of blood were significant and London et al. (1998) found that platelet transfusions were significantly predictive of prolonged ventilation. Although there were three studies reporting association with blood product administration, there is variation between the type and amounts of blood products in each study. This means the findings were not exact replications and therefore the evidence needs to be treated with caution.

A single study found each of the following to be predictive of prolonged ventilation: intraoperative cerebrovasuclar accident (CVA) (Thompson et al., 1997); the dose of the narcotics sufentanil and fentanyl in the anaesthetic (London et al., 1998); the use of an

arterial graft (London et al., 1998); and the time of arrival in ICU (London et al., 1998).

The last of these was considered to be a result of night staff being more cautious in extubating patients operated on at the end of the day because there was less support for emergencies or complications, available at night at this study's centre. The findings of these studies also need to be treated with caution, because of the lack of replication and lack of prospectively collected data.

Two variables may have been identified as possibly causing prolonged ventilation because more than one study reports the finding. The heart's ability to function after surgery appears to be a factor that may be worth some consideration. Three studies, including Cheng et al. (1997) seem to indicate that those patients whose hearts needed either mechanical or pharmacological support intra and/or postoperatively also appeared to need prolonged ventilation. Doering et al. (1998) found that haemodynamic instability in the first three hours postoperatively was also predictive of prolonged ventilation. The second variable is the length of cardiopulmonary bypass (CPB), which may also affect ventilation times. Long CPB times (perhaps 120 minutes or more) may be associated with longer ventilation times (Habib et al., 1996, Thompson et al., 1997 and Rady and Ryan, 1999).

As with the preoperative variables, the data, on which these findings are based, were mostly collected retrospectively, with the exception of Cheng et al's (1997) and Doering et al's (1998) studies. This means that their findings should be treated as inconclusive and that further research is warranted. Cheng et al's (1997) and Doering et al's (1998) findings would be strengthened if they could be replicated in another prospective study.

2.3.3 Summary of the Literature Review of Risk Factors for Prolonged Ventilation

There are many risk factors that researchers have considered may be key in affecting outcome after cardiac surgery with regard to ventilation requirements. The evidence from these studies is inconclusive regarding which variables may predict requirement for prolonged ventilation after cardiac surgery. Most of the studies identified have been based on a single centre patient population, with varied strategies for managing patients, often with a retrospective case review design, some have looked simply at preoperative factors, some intraoperative and postoperative as well, some have studied all types of cardiac surgery, some have focused on CABG, some have looked at variables for heart function and lung function, some have included other organs such as kidney (renal) function, or diseases such as diabetes. The interest in predicting ventilation outcomes is to do with not only identifying patients who can safely be considered for early extubation, but also for planning the type of case mix to maximise and plan resource use. For example, if all the patients on a surgical list on one day are likely to require longer term ventilation it may not be possible to operate on other patients the following day, because all the ventilator equipment is in use.

Preoperative lung function has had varying predictive value in the studies discussed and it appears that it may not to be a factor that should exclude patients from routine consideration for early extubation. Left ventricular function appears more frequently as a factor for patients requiring longer term ventilation, but Serna et al. (1998), found that a significant proportion of their institution's patients with poor left ventricular function were successfully extubated within 6 hours. This suggests that poor left ventricular function may not be a criterion for routinely excluding patients from early extubation protocols. Older patients have been identified as having a higher risk of requiring prolonged ventilation, but once again it does not appear to be a reason specifically to exclude them

from early extubation management, as significant numbers are able to be extubated successfully, without increased morbidity or mortality.

It appears that intraoperative and postoperative events may play a more significant role in patients' requirements for prolonged ventilation. This means that it is extremely difficult to predict a patients' postoperative course before surgery with all the associated resource and planning issues. The development and validation of risk scores, such as Wong et al's work (1999), may well be helpful. This risk score is based on possibly the strongest available evidence to date, because it incorporates factors found to be significant in predicting prolonged ventilation in patients managed for early extubation in a prospective study (Cheng et al., 1997). Further research, including validation of risk assessment scores, is clearly necessary in this area to provide a stronger evidence base for either excluding patients with specific preoperative risk factors from early extubation or for using risk assessment scores when assessing a patient's suitability for extubation.

2.4 SERVICE DELIVERY AND EARLY EXTUBATION

The previous sections of this literature review have focused on the safety of early extubation. This section covers service delivery issues. Many papers in the early extubation literature present an institution's experience of a change of practice from conventional to early extubation of cardiac surgical patients.

Quality improvement initiatives aim to provide quality care at the best possible price, so it is hardly surprising to find that improvements in service delivery often seem to have associated cost savings and these are also discussed in the literature. With increasing pressure to contain costs and to demonstrate quality of care delivery in hospitals, there has

been a number of new developments, often led by the USA. Case management is a model where case managers co-ordinate the care patients receive and is one such development. Other models use staff nurses to co-ordinate care. The assessment of readiness for extubation (particularly for uncomplicated patients) has frequently been delegated to nurses or respiratory therapists (in the USA), rather than doctors leading the decision to extubate, as was the practice in the past. This assessment may be considered an extended nursing role that is often implemented as part of a new programme of managing cardiac surgical patients.

Early extubation protocols, guidelines or specific criteria, sometimes written in the form of an algorithm, to guide the clinicians' decisions when assessing a patient's readiness for extubation are frequently part of the change in management of these patients, and therefore, how the service delivers their care. Often early extubation protocols or guidelines, and the associated anaesthetic protocols that give direction for the type of anaesthesia required to achieve early extubation, are part of care pathways (also known as critical pathways/fast track protocols/fast track pathways) for cardiac surgery. Care pathways and associated protocols or guidelines, are a tool used to facilitate the co-ordination of patients' care. Care pathways are tools that provide a route map of care for patients undergoing similar treatments for similar conditions. They usually describe particular interventions and expected outcomes, which would normally occur at specific time points for patients following a particular course of treatment. As the care pathways document the plan of care, the care that is given and an evaluation of that care, they provide standardised records, which can be used to monitor quality. Care pathways provide details of deviations, usually known as variations, from the pathway that can be evaluated and, if particular problems are identified, the information can be used to improve care (Griffith et al., 1996).

In the cardiac surgery literature care pathways are often known as fast track or rapid recovery programmes, pathways or protocols. Early extubation protocols or guidelines sometimes use an algorithm format for the decision making process. Where care pathways are used, protocols, guidelines or algorithms (an algorithm is a way of presenting criteria one at a time with a yes/no format directing the practitioner to the next criteria if the previous one has been met and directing them to appropriate action if the criteria are not met) are used for individual aspects within the whole pathway. For example, anaesthetic protocols, early extubation protocols, guidelines for the treatment of postoperative atrial fibrillation.

There are a number of papers discussing experiences of implementing care pathways that include early extubation protocols or guidelines as well as a number of reports of the implementation of an early extubation protocol or guideline. Although some of these papers provide audit data to demonstrate some of the outcomes of their individual programme of change (Chong et al., 1992, Alexander, 1994, Massey and Meggit, 1994, Anderson and O'Brien, 1995, Gross, 1995, Howard, 1995, Edwards and Hess, 1996, Griffith et al., 1996, Riddle et al., 1996, Gale and Curry, 1999, Hwang et al., 1999, Goodwin et al., 1999 and Jacovone et al., 1999), they do not provide rigorous evaluations of the implementation process using a research design. Their experiences cannot, therefore, be generalised to all cardiac surgery departments. Their contribution lies in the themes they identify as playing a role in the benefits of early extubation and in implementation process for early extubation. The significance of the contribution of each of these themes, however, is not possible to determine without further research. The themes are discussed in the following sections.

2.4.1 Standardisation of Practice

One of the main reasons for implementing a care pathway (Gross, 1995, Howard, 1995, Griffith et al., 1996, Riddle et al., 1996, Corsetti and Perry, 1998, Sakallaris et al., 2001), or a specific guideline or protocol (Chong et al., 1992, Alexander, 1994, Anderson and O'Brien, 1995, Maxam-Moore and Goedecke, 1996, Davies, 1997, Gale and Curry, 1999) seems to be to reduce variations in practice and to provide high quality, standardised care for patients. Jenkins (1997) in a review of the nursing literature on early extubation discussed the value of using such tools. Jenkins considers that usefulness of assessment tools and, in particular algorithms, lies in the way they can guide nurses through a decision making process and alert them to problems or potential problems along the way. The protocol, guideline or algorithm and care pathway ought to be based on the best evidence available. These tools are useful in setting standard practice and therefore can reduce variations and inconsistencies between different individuals. The dangers associated with such variance are that patients get a varied standard of care and, as a result, some patients may be exposed to greater risks than other patients. Such tools provide ways of assuring the quality of care given and ensure accountability for practice if adhered to by practitioners and they provide legal documentation should it be required. These tools can be criticised for encouraging nurses to adopt a practice without re-examining or questioning that aspect of care, which could discourage innovative practice and individualised patient care. Jenkins (1997) concludes that the preparation involved in developing protocols, providing associated education and auditing changes in practice are important in providing safe care, particularly when a change in care of patients is proposed. It assures the quality of care, provides a framework for accountability and competence of practitioners.

2.4.2 Benefits for the Patient

Early extubation and fast track pathways are not only seen as safe, but the benefits they offer for patients have also been discussed. Benefits such as the reduced risk of postoperative complications, particularly chest infections, which increase the longer a patient is ventilated, are mentioned by Anderson and O'Brien (1995). Alexander (1994) and Jacovone et al. (1999) also mention the reduced risk of postoperative infection offered by early extubation. Other benefits according to Anderson and O'Brien (1995) include: an earlier return to independence; patients being more comfortable once taken off the ventilator, which happens more quickly with early extubation; regaining a normal sleep pattern; and a reduction in the stress of being in an intensive care environment for both the patient and family by returning to a more normal environment earlier (i.e. a hospital ward). Several authors mention the benefit of a quicker recovery and discharge due to earlier commencement of rehabilitation (Chong et al., 1992, Anderson and O'Brien, 1995, Howard, 1995, Gross, 1995, Edwards and Hess, 1996, Griffith et al., 1996, Riddle et al., 1996, Corsetti and Perry, 1998 and Sakallaris et al., 2001). One study, however, provides stronger and more reliable evidence for early extubation patients' quicker recovery. Cheng et al. (1998a) report on data from their randomized controlled trial that patients extubated early resumed their normal mental function, which was measured using the mini-mental state test, significantly earlier than those patients extubated conventionally.

The strongest evidence for early extubation facilitating early discharge from ICU and hospital comes from three of the randomised controlled trials discussed in section 2.2.1 and 2.2.2. Quasha et al. (1980) found that early extubation did not significantly shorten ICU length of stay. Discharge from ICU was, however, affected by several factors such as the willingness of doctors to discharge patients to the ward and the availability of beds. Cheng et al. (1996a) measured the point at which patients were clinically ready to be discharged

from ICU and the hospital. They found that patients who were extubated early had significantly shorter mean (SD) ICU and hospital length of stays. (17.3 (12.1) hours for the early group compared to 25.6 (12.3) hours for the conventional group for ICU length of stay ($p < 0.02$); and 5.7 (2.4) compared with 6.6 (2.4) days for hospital length of stay ($p < 0.02$). Reyes et al. (1997) reported a significantly shorter median (range) ICU length of stay for the early extubation group compared with the conventional group; 27 (1-764) hours and 44 (1-2,030) hours respectively.

Early extubation seems to be associated with earlier discharge from ICU (Cheng et al., 1996a and Reyes et al., 1997) and from hospital (Cheng et al., 1996a). There are however, differences in these two studies definitions of early extubation (discussed in sections 2.2.1 and 2.2.2), which mean the findings have not been exactly replicated and should be treated with some caution.

Many of the benefits for patients identified above, however good they seem, appear to be assumed by the authors, perhaps from observation or anecdotal comments by patients, as valuable to the patients and they do not appear to be based on evidence from the patients themselves. A few papers do present results from patient satisfaction surveys indicating a good level of satisfaction (Riddle et al., 1996 and Sakallaris et al., 2001).

There is a lack of discussion about identifying any concerns patients have about early extubation and none about involving patients in the development and evaluation of fast track pathways. This is perhaps a reflection of the time these papers were published, which was before user involvement became considered to be an integral part of service delivery and organization and associated research.

2.4.3 Benefits for the Institution

One of the main reasons for implementing early extubation guidelines with or without a care pathway is cost containment. Several papers report that their institution reduced the costs of cardiac surgery (Chong et al., 1992, Alexander, 1994, Massey and Meggit, 1994, Gross, 1995, Karski, 1995, Edwards and Hess, 1996, Griffith et al., 1996, Riddle et al., 1996, Jacovone et al., 1999 and Sakallaris et al., 2001). None of these papers appear to base their findings on a rigorous economic evaluation. However, a reduction in each patient's length of stay in the intensive care unit and in hospital should be associated with cost savings because their care is using fewer resources. This is the basis of the argument for early extubation reducing costs. It seems likely that costs are reduced, but this varies from institution to institution depending on how they calculate the price of a cardiac operation. There is also variation in the ICU and hospital length of stays achieved by different institutions approaches to early extubation and care pathways. Cost savings will, as a result, differ according to the practices adopted by each institution.

Cheng et al. (1998b) describe the elements of a patient's cardiac surgery episode, showing where different costs, from different anaesthetics and cardiac surgical techniques, to staff costs, to costs of tests, to costs of complications and differences in institutions' organisation of cardiac services (e.g. the use of preadmission clinics) should be considered in an economic evaluation. Although early extubation has an effect on reducing ICU and hospital length of stays and does not appear to increase complication rates, many other factors also influence ICU and hospital discharge and need to be taken into consideration by clinicians and managers planning changes in their services.

Another organisational issue that has slowed the throughput of cardiac surgical patients is lack of availability of ICU beds. Some centres have set up cardiac surgical recovery areas

(CSRA) to address this problem (Westaby et al., 1993, Massey and Meggit, 1994, and Howard, 1995). These units are designed to support cardiac surgical patients in the immediate postoperative period, where they would be extubated as early as possible and moved to a high dependency area. This means the CSRA beds, equipped with ventilators and other ICU type equipment, could be reused several times a day. Westaby et al. (1993) successfully used a three-bedded CSRA for a thousand patients between January 1990 and June 1991. They were able to reuse the CSRA beds allowing 5 to 6 operations a day. They also report a difference in nursing staff compliment of 4.5 per bed compared with 7.8 for an ICU bed in their institution at the time. They concluded it had been a successful and cost effective way to tackle problems with ICU bed availability.

Whether a CRSA is used or simply a care pathway, including early extubation, in a more traditional ICU setting, there seems to be a consensus that one result is the improved planning for the smoother throughput of cases (Chong et al., 1992, Westaby et al., 1993, Alexander, 1994, Anderson and O'Brien, 1995, Howard, 1995, Karski, 1995 and Sakallaris et al., 2001). Associated with this smoother throughput of patients is the better use of resources (Chong et al., 1992, Westaby et al., 1993, Massey and Meggit, 1994, Anderson and O'Brien, 1995, Howard, 1995, Karski, 1995, Edwards and Hess, 1996, Riddle et al., 1996 and Corsetti and Perry, 1998..

2.4.4 The Implementation Process

A number of papers describe their experiences of implementing an early extubation guideline and fast track programmes and authors identify aspects they considered important in facilitating the process. The strength of the evidence for successful implementation they provide is limited and means that the application of these ideas should be considered with caution. These papers' limitations are because they are individual cases and the points

raised are not based on rigorous research. However, if the practices described are similar to a particular local situation they may provide some useful insights.

Karski (1995) describes aspects of early extubation that need to be taken into consideration by practitioners considering changing the management of their cardiac surgical patients.

Karski suggests that developing a protocol for intraoperative and postoperative care and selecting low risk patients to start with, will enable the team to gain experience. Once the practice is established and the team experienced, the author suggests that the protocol can be widened to include a broader range of patients. The aspects of care Karski recommends for consideration are the anaesthetic technique, cardiopulmonary bypass (i.e. – keeping the body warmer than traditionally done and minimising the volume of fluids administered), using a short acting agent, such as propofol, for postoperative sedation, the management of shivering, early extubation, pain control, haemodynamic control, postextubation monitoring, transfer out of ICU.

Planning the implementation of a new pathway or guideline is also recommended (Griffith et al., 1996, Keresztes and Kuruzar, 1996, Maxam-Moore and Goedecke, 1996, Jacovone et al., 1999 and Sakallaris et al., 2001). Keresztes and Kuruzar (1996) presents a case study of a patient who was extubated in the operating room (theatre) and its impact on and implications for the nurses caring for the patient in the postoperative period. Keresztes and Kuruzar write that this case was unplanned and therefore proved a challenge, as the nursing care required was different from what the nurses were used to. They felt inadequately prepared for this case and the author points out that the use of protocols or guidelines and the associated planning and education prior to a change in management of patients helps to avoid this sort of situation.

In contrast Griffith et al. (1996), Maxam-Moore and Goedecke (1996), Jacovone et al., (1999) and Sakallaris et al. (2001) found the use of planning a change in practice, including the development of protocols or pathways and piloting or trialing the change helped the process of implementation. The use of a pilot allowed evaluation of the plan and any adjustments to be made prior to developing a rapid recovery programme for their cardiac surgical patients from the results of their pilot. The rapid recovery programme incorporated changes to the extubation protocol. It also focused on a more aggressive approach to activity earlier after surgery and early transfer to a step down unit.

Although Hwang et al's (1999) experience of changing practice, does not appear to have been as structured as programmes discussed above, they comment on how the introduction of a new practice by some clinicians was gradually accepted by others as the benefits were experienced and demonstrated in audit data. This experience also indicates the value of a pilot or small-scale implementation prior to a full implementation in helping clinicians adjust to the change.

Gale and Curry (1999) also discussed the resistance to change they experienced when changing practice to nurse-led early extubation. They had different experiences with the nurses and the doctors involved. They considered barriers to the implementation of their guideline and in particular cultural resistance. They designed and delivered an education programme to facilitate the change in practice for the nurses and this was considered successful for this purpose. As well as theoretical and practical sessions on the guideline, nurses were given the opportunity to reflect on the new guidelines using discussion of critical incidents and the strengths and weaknesses of the guideline implementation project. There was some resistance among the doctors and the authors felt this was eventually overcome by persistently promoting available evidence, rather than by any particular model

of change management. Gross (1995) also found that an education programme was an important part of the implementation and Sakallaris et al. (2001) found that the use of a facilitator for the project early on, celebrating the results and considering the programme as ongoing were beneficial in promoting the change in practice.

The number of papers written by nurses mentioned the importance of collaborative working between members of the multidisciplinary team to ensure a successful change in practice (Alexander, 1994, Anderson and O'Brien, 1995, Gross, 1995, Griffith et al., 1996, Riddle et al., 1996, Corsetti and Perry, 1998 and Sakallaris et al., 2001). Howard (1995) and Gale and Curry (1999) also commented that the process of implementing early extubation had improved multidisciplinary team working.

2.4.5 The Nurse's Role

The introduction of early extubation has often been associated with an extension in the nurses' role. Westaby et al. (1993) and Massey and Meggit (1994) managed the care of patients in their CSRA using specially trained nurses taking the lead with support from cardiothoracic surgeons and anaesthetists. Papadakos and Early (1995) describe changes in the roles of clinical nurse specialist and respiratory therapists, who took a lead in weaning and extubation in their centre in the United States of America (USA). In a number of other centres (Alexander, 1994, Anderson and O'Brien, 1995, Howard, 1995, Corsetti and Perry, 1998 and Gale and Curry, 1999), nurses were also trained to assess patients for extubation and make the decisions to extubate.

Some centres, however, decided that doctors should still make the final decision to extubate a patient (Edwards and Hess, 1996 and Hwang et al., 1999). Jenkins (1997), in her review of nursing literature, noted that nurses seem to be in the best position to take on the role of

extubating patients, as they remain at the patients' bedside during the recovery period. She identified several themes emerging from the discussion that were important in facilitating this extended role for the nurse. Education and gaining the appropriate clinical skills were key factors, as was the use of comprehensive assessment tools used to guide nurses through the decision making process. In some centres a clinical nurse specialist or other nurses played an important and often co-ordinating role in planning and implementing a care pathway (Maxam-Moore and Goedecke, 1996, Davies, 1997, Corsetti and Perry, 1998, Gale and Curry, 1999 and Jacovone et al., 1999). Research to investigate the impact of nurses' extended roles on patient outcomes is needed.

2.4.6 Summary of Service Delivery and Early Extubation

The introduction of early extubation guidelines is almost always associated with other changes in the management of cardiac surgical patients. Sometimes this is planned, as with this introduction of a care pathway for the whole patient episode, or is the result of the possibility of earlier rehabilitation and discharge for hospital because patients are not spending so long in intensive care units. The literature on these service delivery considerations, consists mainly of descriptions of individual centres' experience of implementing such a change.

Although several themes (standardisation of practice, benefits for the patient, benefits for the institution delivering cardiac surgery, the implementation process, and the nurses role) arise from the literature that seem important when implementing an early extubation guideline or a fast track programme, there is as yet no rigorous research evaluation of the significance and contribution of each. However, the randomised controlled trials discussed in section 2.1 and 2.2 of this review contribute stronger and generalisable evidence to early extubation facilitating early discharge from ICU and hospital. Earlier discharge offers

benefits to the patient, such as earlier commencement of rehabilitation, earlier resumption of usual activity and a shorter stay in hospital, and benefits to the institution, in particular cost saving and improved resource use.

2.5 LITERATURE REVIEW CONCLUSIONS

Early extubation has been widely adopted in adult cardiac surgery centres. It seems a safe practice because it does not appear to increase the risk of morbidity or mortality when compared to conventional extubation. The evidence base for early extubation has some limitations. The majority of studies provide grade C (Phillips et al., 2001) evidence and some present audits of a single centre's experiences (grade D). There are some randomised controlled trials (RCTs) that provide grade A evidence (Phillips et al., 2001). It could be argued that these trials are actually grade B evidence because of some methodological weaknesses, in particular the samples do not appear to have been based on power calculations to determine clinically significant effects. There are differences in the methodologies of the RCTs reviewed that limit the comparisons between their findings, such as different study populations and definitions of early extubation. A well-designed, multi-centre randomised controlled trial would provide additional stronger evidence. Alternatively a systematic review of existing clinical trials, including a meta-analysis would also be valuable. It would ensure a systematic literature search that may identify other, possibly unpublished, trials that were not identified in this literature review. A meta-analysis would enable existing data to be pooled. This analysis could take into consideration the differences in sample sizes and research protocols, which would make the conclusions drawn more reliable than those of this review.

The evidence for which preoperative, intraoperative and postoperative variables predict an increased risk of prolonged ventilation seems inconclusive. Most studies have used

retrospectively collected data. This limits the reliability of any causal links found between any variables and prolonged ventilation. Many of them have investigated a range of different variables and some of the results appear conflicting between studies. Within the limitations discussed, there may be some indications of which factors could be associated with an increased risk of prolonged ventilation.

Factors associated with poor heart function, either preoperatively or during and after surgery, may be associated with prolonged ventilation because a number of studies have indicated there might be a link. However, patients with poor preoperative heart function have been successfully managed using an early extubation guideline. Prolonged cardiopulmonary bypass time (e.g. greater than 2 hours) has also been associated with prolonged ventilation in some studies, but not in others. Conflicting findings for existing lung disease (e.g. asthma or chronic pulmonary obstructive disease) means it may or may not be a predictive factor for prolonged ventilation. Older age has also been found in a number of the studies to be associated with an increased risk for prolonged ventilation, but there is also some evidence that older patients can be successfully managed using an early extubation guideline.

More prospectively designed studies would help clarify which, if any, factors increase the risk of prolonged ventilation. Risk scores developed from such prospective studies also offer the opportunity to test the effectiveness of using the identified risk factors to determine clinically significant prolonged ventilation times.

Research evidence is lacking for the effectiveness of service delivery considerations related to early extubation. In particular, there does not appear to be any rigorous research evaluation of strategies used either to implement an early extubation guideline or a care

pathway that includes an early extubation guideline. The review of papers describing, usually, single centre implementation experiences, has identified several recurring themes that relate to implementing an early extubation guideline. These are: standardising practice, benefits for the patient, benefits for the institution delivering the service, the implementation process and the nurse's role in both early extubation and the implementation process. More research in this area is clearly needed to investigate the effectiveness of implementation strategies and their effects in standardising practice, the benefits they bring to patients and the institution, as well as the effectiveness of the roles nurses play in early extubation and its implementation.

CHAPTER THREE

METHODOLOGY

3.1 INTRODUCTION

This study is evaluation research. It aims to examine the effects of a health care intervention, i.e. the implementation of a clinical guideline for nurse-led early extubation of adult cardiac surgical patients. It also attempts to examine the circumstances in which the guideline was implemented and to assess the effectiveness of the implementation (Bond, 2000). The three parts of the study each use a different research methodology, a systematic review of quantitative research on the safety and efficacy of early extubation for adult cardiac surgical patients, an interrupted time series study and a qualitative study, drawing on applied practitioner ethnography. These last two parts aim to investigate the implementation of a clinical guideline for nurse-led extubation of adult cardiac surgical patients at one centre in the United Kingdom, while the first part aims to investigate the evidence base for the practice of early extubation.

3.2 RESEARCH QUESTION AND OBJECTIVES

The research question for this study is, "Does standardising nursing practice through the implementation of a clinical guideline for extubating adult cardiac surgical patients early improve patient care?" It has three specific objectives that are addressed through three linked parts:

1. To provide a systematic overview of the evidence base for early extubation of adult cardiac surgical patients (Hawkes et al., 2003).
2. To quantify the impact on professional practice of standardising care through the use of a clinical decision guideline for nurse-led early extubation of adult cardiac surgery patients (interrupted time series).

3. To explore reasons for the results of the interrupted time series and to identify important factors for the successful implementation of a clinical decision guideline for the early extubation of adult cardiac surgical patients by nursing staff (qualitative part drawing on applied practitioner ethnography).

The focus of the study is to measure the impact of the extubation guideline on nursing behaviour to improve patient outcomes, and to contribute to the literature on the effectiveness of guidelines for clinical practice. The systematic review looks at current evidence available on the safety and efficacy of early extubation in adult cardiac surgical patients. The review presents and synthesises the evidence systematically to reduce bias and, therefore, strengthen the reliability and validity of the conclusions. The results are available to feed into reviews of the guideline by the nurses at the research site, as well as being available to clinicians at other centres through the Cochrane Library (Hawkes et al., 2003). The quantitative data, from the interrupted time series analysis, are used to show the impact of the extubation guideline on nursing behaviour and patient outcomes. The qualitative data are used to highlight anything that may have occurred on the unit, during the implementation process, which may have affected or may help explain the results of the interrupted times series data. These qualitative data also give a more in-depth view of the process of implementation. As the researcher was an insider (a clinician) on the unit (research site), the qualitative study drew on applied practitioner ethnography although it did not use participant observation for data collection. This applied use of ethnographic methods and methodology is explored further in chapter six.

3.3 RATIONALE FOR CHOICE OF METHODS

The current study has used triangulation of research methods, using both qualitative and quantitative methods. Triangulation has been used in different ways in research: between types of data; between investigators with different skills and experiences; between theoretical approaches to research design; between methodological approaches and in analysis (Begley, 1996). Evaluation research commonly makes use of some or all of these types of triangulation. The aim of using the different methods in this study was to provide completeness (Begley, 1996, Tobin and Begley, 2004, Borkan, 2004). Tobin and Begley (2004) discuss the concept of completeness and suggest that using triangulation in research methods can create a more comprehensive (or complete) view of the subject of the research project than would be achieved through a single method investigation.

This study is based at a single research site, a specific hospital unit, and could be regarded as a single case study of a development and implementation of a clinical guideline. One of the values of case study research is that it offers the opportunity to study a phenomenon in its natural environment (Yin, 1994) so that a real life situation is not distorted by experimental conditions (Pontin, 2000). Triangulation has also been considered to improve the internal validity of single case study research (Yin, 1994 and Pontin, 2000). If the findings from the different methods used converge, validity is strengthened because the potential biases or errors made in any one methodology are likely to have been exposed in others (Tobin and Begley, 2004). Conversely there could be a risk that bias or errors could be compounded by triangulation. However, a carefully and thoroughly planned research design should help to minimise this risk (Begley, 1996).

Issues of validity and reliability for case studies are discussed extensively in the literature (see Rolfe (1998) for a helpful summary of the issues). Case studies are often considered

qualitative research. It is suggested that it is better to use criteria more suited to the qualitative research paradigm, rather than simply trying to apply assessment strategies from the positivist quantitative tradition when appraising the validity and reliability of a qualitative study.

A single case study could be criticised for not providing any information that could be generalised to the population when viewed from a quantitative stance. However, if the presentation of the methodology and the context of the qualitative study are clear and the potential biases are explored, this is a way of giving the reader opportunity to assess the validity of the study and its usefulness for the reader's own context. This type of presentation and exploration was conducted in the qualitative part of the current study (see chapter six). The reader can make their own assessment of the transferability of the findings to other similar settings. However, because the systematic review and the interrupted time series take their methods from the positivist paradigm using quantitative methods, they provide findings that can stand alone, as well as contributing to the internal validity of the case study, and their findings can be generalised to the wider population they investigate, that is, adult cardiac surgical patients in the National Health Service in the United Kingdom. Case studies, by their nature of using a variety of sources of data and methodologies, often overlap with other research designs and strategies (Pontin, 2000). The overlap in the current study is that, while each part of the design could stand alone, when combined they provide a more complete picture of the phenomenon of developing and implementing a clinical guideline for early extubation of adult cardiac surgical patients by nurses.

Each of the methodologies used for the different parts of the study also pose issues of reliability and validity, which will be discussed later. In particular, the interrupted time

series design has been chosen to address problems of reliability and validity raised by before and after intervention quasi-experimental research designs. The design itself offers the possibility of generalising the findings to similar patient populations and can be regarded as quantitative research. The three following chapters present the methodologies of the three parts of the study; the systematic review (chapter four), the interrupted time series (chapter five), and the qualitative study (chapter six).

3.4 ETHICAL CONSIDERATIONS

Ethics approval was sought and gained from both the University Research Ethics Committee and the Local Research Ethics Committee for the research site.

A key ethical issue was the use of patient records in research and gaining informed consent. It was agreed with the Local Research Ethics Committee that it would be an extremely difficult task to trace patients retrospectively and gain their consent to use information in their medical records for the research. The committee agreed that the data collected retrospectively for the year prior to the implementation of the guideline could be collected with assurances that it would be anonymised. For the prospective data collection, all patients who were electively admitted to the research site for first coronary artery bypass surgery were sent a letter and an information sheet about the project, prior to admission. They were invited to opt out of the study if they so wished by returning a reply slip in a prepaid envelope to the researcher. If they did not reply, their information could be used as part of the study. The researcher received one enquiry about the study. One person requested to opt out of the study, however this persons' operation date eventually fell outside the timescale of the study. Their data were, therefore, not included.

The researcher's dual role as a clinician at the research site and a researcher raised several issues. The effect on the interviewees' agreement to participate in the research was considered. Strategies to minimise implicit coercion were developed, such as informed consent. The concern was that the participants might have felt under some sort of obligation to participate in the research, as the researcher was also a colleague. Invitations to be interviewed were sent to potential participants with a reply slip they had to return if they wanted to participate in the study. The researcher made no other contact with the potential participants to encourage them to participate. The potential biases in the data given by interviewees and in the researcher's interpretation of the data were other issues. The design of the qualitative part allowed for exploration of these issues by asking participants for their views on the researcher's roles (see chapter six).

CHAPTER FOUR

METHODOLOGY OF THE SYSTEMATIC REVIEW OF EARLY EXTUBATION FOR ADULT CARDIAC SURGICAL PATIENTS

4.1 WHAT IS A SYSTEMATIC REVIEW?

Chalmers and Altman (1995, p.5), define a systematic review as “ a review that has been prepared using a systematic approach to minimising biases and random errors which is documented in a materials and methods section. A systematic review may, or may not, include a meta-analysis: a statistical analysis of the results from independent studies, which generally aims to produce a single estimate of a treatment effect.”

Concerns over the quality and reliability of traditional narrative literature reviews were raised in the 1980s by work of Mulrow (1987) and discussed by Egger et al. (2001) and work by Oxman and Guyatt (1988). Concerns included, bias in the selection of studies reviewed, invalid summaries based on the evidence presented in the articles, publication bias, poor quality of the studies reviewed and inappropriate meta-analysis. Since then there has been a considerable amount of work done on developing reliable and valid methods of reviewing medical literature, in particular by organisations such as the Cochrane Collaboration and the NHS Centre for Reviews and Dissemination at York University. One of the key advantages of a systematic review is that it weighs up the often contradictory research evidence by giving most credit to the highest quality research with the most reliable results.

4.2 WHY A SYSTEMATIC REVIEW?

The early extubation guideline developed by clinicians at the research site used evidence from research papers obtained by the project group's own literature search. This was because a relevant systematic review of the safety and efficacy of early extubation was not available at the time. The volume of literature published on each aspect of a health care professional's practice can be enormous and it is difficult continuously to keep up to date. Reliable and unbiased reviews are therefore an important source of information to facilitate decision making for practice. Therefore, as part of this study, a systematic review of early extubation, with a sub-group analysis of the health care professionals undertaking the extubation, was registered with The Cochrane Collaboration (2005) and completed under the guidance of the Cochrane Anaesthesia Review Group (CARG) (Hawkes et al., 2003).

The Cochrane Collaboration (2005) is an international organisation that aims to help people make well-informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions. The Cochrane Collaboration provides training for reviewers. Reviews are conducted systematically, following a protocol. The researcher submitted the protocol to the Cochrane Collaboration for peer review and approval before the review was conducted. The same process occurred with the report of the systematic review, which was then published by the Collaboration (Hawkes et al., 2003). Systematic reviews include meta-analysis, where possible.

The completed systematic review is available to inform subsequent revisions to the evidence base of guideline for early extubation of cardiac surgery patients at the research site. It has been published on the Cochrane Collaboration's electronic database (Hawkes et al., 2003) and it is also available for clinicians in other centres and other interested parties.

The new knowledge provided by a Cochrane Collaboration Systematic Review is the rigorous appraisal and synthesis of all existing evidence and it offers the possibility of identifying areas for further research.

4.3 QUALITY OF THE STUDIES INCLUDED IN A SYSTEMATIC REVIEW

Ideally the research reviewed in a systematic review should be of high quality and should provide valid and reliable results, otherwise the systematic review will not be reliable and valid. The gold standard for research methodologies for medical interventions is the randomised control trial (Muir Gray, 2001). These types of study provide results that can be generalised. Other methods such as controlled clinical trials, cohort studies and other observational studies are also important, but have an increased risk of introducing bias as the participants are not always randomised to treatment and non-treatment groups, nor is the sample randomly selected from a particular population. Cochrane reviews focus on the research that provides the most reliable results. They, therefore, often focus on randomised control trials and controlled clinical trials and sometimes include interrupted time series.

The risk of introducing bias in randomised control trials does exist and therefore systematic reviews include a quality selection process. These risks are selection bias (where patients in the treatment and non treatment groups are not randomly allocated to study groups), performance bias (where the two groups have different treatment other than the intervention under investigation), detection bias (where the assessment of outcomes is biased), and attrition bias (which is due to exclusion of patients who drop out of the study along the way), (Egger et al., 2001). The researcher and a co-reviewer (a consultant anaesthetist identified for the researcher by CARG) independently assessed the study quality for the reviews included in the systematic review. An assessment tool from the

Cochrane Anaesthesia Review Group was adapted and used for the quality assessment process (see Appendix B).

Other sources of bias in literature reviews include publication bias. This occurs where published research evidence is biased towards positive results, and such studies are more likely to be published in English, published more quickly, published more than once and cited more often, than studies which show no advantages or disadvantages to the intervention under investigation. The research sponsor can also contribute to publication bias, with government-funded research more likely to be published than that funded by pharmaceutical companies (Egger et al., 2001). For this reason, in a systematic review, as with this one, efforts are made to identify unpublished data, for example through personal contact with authors, or key researchers in the field, searching grey literature.

Reporting bias is also another danger to reviewers. This occurs when the author of a paper presents a biased view of the results of their study. In a systematic review this can be overcome, by extracting raw data from papers (or by contacting authors for more details) and comparing the raw data from several studies. The outcomes of interest in the review are identified before searching the literature, to avoid introducing reporting bias in the systematic review. In this study the outcomes of interest are stated in the protocol below.

4.4 PROTOCOL FOR THE SYSTEMATIC REVIEW

4.4.1 Objectives

The objective of the systematic review was to establish the safety and efficacy of early extubation for adult cardiac surgical patients. Five hypotheses were investigated. These were:

1. Postoperative mortality for adult cardiac surgical patients is not affected by the time of extubation (early extubation versus conventional extubation).
2. Postoperative morbidity (as specified in the criteria section 4.4.2) for adult cardiac surgical patients is not affected by the time to extubation (early extubation versus conventional extubation).
3. The duration of stay in the postoperative intensive care unit is less for adult cardiac surgical patients extubated early compared with those extubated conventionally.
4. The duration of postoperative stay in hospital is less for adult cardiac surgical patients extubated early compared with those extubated conventionally.
5. The types of staff (medical versus non-medical) who decide when adult cardiac surgical patients should be extubated do not affect these outcomes.

A subgroup hypothesis was also investigated. This was:

- The outcomes (as specified in the criteria section 4.4.2) are not affected by the time of early extubation for adult cardiac patients in the following subgroups: less than four hours; four to eight hours; greater than eight hours (see types of intervention).

4.4.2 Criteria for Considering Studies for this Review

4.4.2a Types of studies

Randomised Controlled Trials (RCTs), Controlled Clinical Trials (CCTs) were the types of studies included in the systematic review.

4.4.2b Types of participants

The types of study participants included in the review were adult (aged 18 years and over) cardiac surgical patients who had had the following types of surgery:

- coronary artery bypass grafts (CABG);
- aortic valve replacement (AVR);

- mitral valve replacement (MVR);
- aortic aneurysm repair
- or combinations of the above.

Children were excluded from this systematic review as they tend to respond differently to cardiac surgery and often have different types of cardiac surgery.

4.4.2c Types of intervention

Studies investigating two interventions were included in this review. The first intervention was extubation of cardiac surgical patients within eight hours of surgery. The second intervention was the healthcare professional who decides when to extubate these patients.

Eight hours was the definition of early extubation for the first intervention investigated. This was because, during the 1990s, the term 'early extubation' was applied to the patients who were allowed to wake up from their surgery as soon as they were stable and able to maintain their own airway safely. In the literature, early extubation is frequently defined as within eight hours of surgery. In contrast, the conventional practice was to sedate and ventilate all patients overnight (see chapter two, section 2.1 for more details). Early extubation within eight hours of skin closure is, therefore, a practical rather than biological definition (i.e. it is not based on an established physiological effect or reason). The change to early extubation was prompted by the desire to contain the costs of cardiac surgery and it was facilitated by the change from high dose opiate anaesthesia to low dose opiate supplemented with propofol or etomidate or volatile anaesthesia (sometimes referred to as 'fast-track' anaesthesia, see chapter 2, section 2.1).

As there is no biological reason for choosing eight hours for the cut off point for early extubation and because recent interest (Mcguire et al., 2000) appears to be in the safety and

efficacy of immediate extubation, a sub group analysis was planned. This analysis aimed to see if the outcomes were the same for groups by manipulating the timing of the intervention. The plan was to sequentially alter the inclusion criteria for studies on the basis of timing of the intervention, from less than four hours to less than eight hours to more than eight hours.

Extubation time was defined as from skin closure to extubation. Some units extubate in the operating theatre, whilst others transfer to a recovery area or ICU, so using skin closure to extubation should be applicable to all practices.

The plan for investigating the second intervention (the healthcare professional who decides when to extubate the adult cardiac surgical patients) was to compare the outcomes for patients who were extubated by medical staff with the outcomes for patients extubated by all other healthcare professionals grouped together. At the study site extubation of cardiac surgical patients was an established nursing practice, however different centres have different professions making this decision. It is possible that differences in professional background, working and training could affect the outcomes so the systematic review included this intervention to see what effect, if any, the profession of the clinician deciding when to extubate had on the outcomes.

4.4.2d Types of outcome measures

Several primary and secondary outcome measures were selected for the systematic review. These are presented below with their associated hypotheses and a rationale for their selection.

Primary Outcomes:

1. Mortality rates (death rates), with analyses conducted for intensive care unit (ICU), early and late mortality.

Hypothesis: The mortality rate is not dependent on time of extubation after cardiac surgery for adults.

Rationale: The role of early extubation in mortality is more likely to be significant during the ICU stay than later, as it might contribute to acute respiratory failure or the development of respiratory complications in the immediate postoperative period. Thirty day mortality is a fairly standard mortality outcome measure in studies. Early extubation probably has a less significant role in longer term mortality, but if reported in studies, it might contribute evidence to this hypothesis and so it was included. The mortality rate outcomes investigated were:

- 1) Mortality in intensive care
- 2) Thirty Day mortality
- 3) Mortality between 31 days and one year

2. Incidence of postoperative myocardial ischaemia (damage to the heart muscle caused by reduced blood flow).

Hypothesis: The incidence of postoperative myocardial ischaemia is not dependent on the time until extubation after cardiac surgery for adults.

Rationale: A broad based definition of postoperative myocardial ischaemia was used. Different studies used different criteria or diagnostic tests to define ischaemia, and having a specific definition would have excluded studies from the analysis, perhaps simply because a particular test or scan was not available at the time of the study. Although including a broad definition and amalgamating different types of ischaemia makes the results less specific, it gives the readers some broad guidance on this particular outcome measure. The

definition of ischaemia included any or all of the clinical, electrocardiographic and haematological criteria used to diagnose myocardial ischaemia.

3. Postoperative lung function

Postoperative lung function was investigated using the following outcome measures:

a) Reintubation rates

Hypotheses: Reintubation rates within 24 hours of extubation are not dependent on time to extubation for adult cardiac surgical patients.

Reintubation rates after 24 hours of extubation are not dependent on time to extubation for adult cardiac surgical patients.

Rationale: This outcome measure is a key way of assessing the failure of a decision to extubate. Reintubation rates within 24 hours was the main focus, as after that time factors other than extubating a patient too early are more likely to be the main reason for reintubation. However, data were also collected on the reintubation rates after 24 hours and the reasons for the reintubation.

b) Respiratory dysfunction

Hypothesis: Respiratory dysfunction is not dependent on time to extubation for adult cardiac surgical patients.

Rationale: Respiratory dysfunction occurs in all adult cardiac surgical patients as a result of the surgery and use of cardiopulmonary bypass and it is difficult to assess the effects of extubation on lung function. However, although all adult cardiac surgical patients will have some reduction in lung function, the hypothesis was that these reductions are no different from patients who have undergone conventional extubation. Various measures are used to

assess respiratory function, so these were reported on qualitatively (i.e. descriptively). It was anticipated that a range of outcomes would have been studied including: atelectasis (collapsed areas of lung tissue), PaO₂ and PaCO₂ levels (levels of oxygen and carbon dioxide in the arterial blood), intrapulmonary shunt (a measure of how much blood is not being oxygenated in the lungs because areas of collapsed lung tissue), and arterial/alveolar gradient (the difference in oxygen levels between the blood in the lungs and the blood in the arteries).

Secondary Outcomes:

Two secondary outcomes were investigated. The outcome measures are presented below with their hypotheses and then the rationale for both.

1. Intensive care unit (ICU) length of stay.

Hypothesis: The duration of stay in the postoperative intensive care unit is less for adult cardiac surgical patients extubated early.

2. Hospital length of stay.

Hypothesis: The duration of postoperative stay in hospital is less for adult cardiac surgical patients extubated early.

Rationale: Using hospital length of stay and ICU length of stay as an outcome measure always raises the issue that actual length of stay may be influenced by logistical reasons rather than purely clinical readiness for discharge. However, these measures have been included as secondary outcomes to give readers an indication of the effect of early extubation in adult cardiac surgical patients on ICU and hospital length of stay. It is assumed, in the RCTs included in the review, that these measures of ICU and hospital length of stay were standardized.

4.4.3 Search Strategy for Identification of Studies

The Cochrane Anaesthesia Group search strategy was used as a basis for the search strategy presented below.

4.4.3a Databases and other sources used for the search

The following databases were searched: The Cochrane Library (issue 1, 2003), MEDLINE (January 1966 to June 2003), EMBASE (January 1980 to June 2003), CINAHL (January 1982 to December 2002), and SIGLE (January 1980 to December 2002).

MeSH was used for MEDLINE and other headings appropriate to other databases, such as cardiac surgery, ventilation, postoperative ventilation, extubation, fast track.

The Cochrane Central Register of Controlled Trials (CENTRAL) (issue 1, 2003) was also searched.

The reference lists from the articles and papers identified from the database searches were searched for other relevant studies. Prominent authors in the field were contacted for knowledge of unpublished trials. There was no language restriction on articles selected for the review.

4.4.3b Search strategy

The Cochrane Reviewers' Handbook's (Clarke and Oxman, 2000) suggested search strategy for MEDLINE was used and similar strategies for the other databases for the terms RCT and CCT. The search strategies for MEDLINE, EMBASE and CINAHL are included in Appendix C.

4.4.4 Methods of the Review

4.4.4a Trial identification

Trials included in the systematic review were selected based on the search strategy. The researcher scanned the titles and abstracts of reports identified by electronic searching to produce a list of possible relevant studies. Full text versions were obtained and were independently assessed by the researcher and a co - reviewer identified by the Cochrane Anaesthesia Review Group (Dr Srinisvisan Dhileepan). Disagreements were resolved by meetings between the researcher and the reviewer.

4.4.4b Methodological quality assessment

The researcher and the co- reviewer independently assessed the quality of the studies according to the criteria described by Schulz et al. (1995). They assessed the methods of adequacy of study design, randomisation (including quality of concealment of allocation), and description of withdrawals.

4.4.4c Data collection

The researcher and the co-reviewer independently extracted the data using the Cochrane Anaesthesia Review Group's (CARG) data extraction form, adapted for this review (See Appendix B). They extracted information on the following: randomisation; anaesthetic technique and criteria for extubation; which healthcare professional carried out extubation; and outcomes identified above in section 4.4.2d.

The researcher contacted authors for missing data. The researcher wrote to all the authors of the included studies at the contact addresses given on their papers. Addresses and whether they still worked there were confirmed by accessing the web sites of the authors' institutions. The researcher asked for any unpublished data on the outcomes that were

included in the review. The researcher also asked them whether they knew of any other clinical trials relevant to the safety and efficacy of early extubation. Professor Quasha (Quasha et al., 1980) no longer had the data. Dr Reyes (Reyes et al., 1997) provided data on several outcomes and on quality issues. Dr Santamaria (Silbert et al., 1998) has indicated that he will provide data that will be included in future revisions of this review published in the Cochrane Library.

The researcher also wrote to Mr Gale (Gale and Curry, 1999) and Dr Moffatt (Wood et al., 1995) for information on any clinical trials or other research studies about the impact of different healthcare professionals on extubating cardiac surgical patients. Dr Moffatt was not aware of any such studies.

4.4.4d Statistics

The data were reviewed qualitatively (i.e. descriptively) and, where possible, combined quantitatively (meta-analysis) using the Cochrane Collaboration's statistical package, RevMan Analyses 1.0.1 (2003).

The meta-analysis used two summary statistics to determine the size of the effect of the intervention on the different outcomes. The relative risk (or risk ratio) was used to analyse outcomes with dichotomous data and the weighted mean difference was used for outcomes with continuous data.

The relative risk was selected, rather than the alternative odds ratio, because it is less likely to be misinterpreted. If an odds ratio is misinterpreted an overestimate of the effect of the intervention is likely and this would have undesirable implications for clinical practice (Deeks et al., 2004). The weighted mean difference is the difference between the mean

value of the study and control groups in the included studies. The weighted mean difference can be used when the scales used to measure the data in the different studies are the same. Each mean is given a weight according to the reliability of the results in a particular study. The reliability is estimated by using the sample size and standard deviations. Studies with smaller standard deviations that indicate more reliable results are given a greater weight than studies with larger standard deviations (Deeks et al., 2004).

One subgroup analysis was proposed for the hypothesis presented in the objectives (section 4.4.1). The subgroups of early extubation were less than four hours, four to eight hours, and greater than eight hours. This analysis was planned to alter sequentially the inclusion criteria for studies based on the timing of the intervention, from less than four hours to less than eight hours to more than eight hours.

Both a random effect and a fixed effect model were used to analyse the data. A random effect model includes the assumption that studies are estimating different, but related effects of treatment. The random effects model, therefore, incorporates the possibility of heterogeneity (variability between studies). The fixed effect model assumes that the studies are estimating the same effects of treatment. It assumes that any heterogeneity is a result of chance and does not take it into account (Deeks et al., 2004).

The results (chapter seven) are presented based on an assessment of the impact of heterogeneity on the meta-analysis. The I^2 statistic was used to assess the impact of any inconsistencies across studies on the meta-analysis. This is recommended (Deeks et al., 2004) as a more useful way of assessing the impact of inconsistencies, which are inevitable, between studies, on the meta-analysis rather than simply identifying the level of

heterogeneity. A result of 50% in the I^2 statistic is considered to indicate a significant impact on the meta-analysis.

The results are presented using the fixed effect model because the I^2 statistic was 0% for all the comparisons. This result (0%) indicated that there was no significant impact of any inconsistencies between the studies on the meta-analysis. When this is the case both the fixed effect and the random effect models have the same result (Deeks et al., 2004) and a presentation of the random effect model results was not necessary.

4.5 THE CONTRIBUTIONS OF THE RESEARCHER AND CO-REVIEWERS TO THE SYSTEMATIC REVIEW

The researcher developed the protocol with assistance from the co-reviewer Dr Srinivasan Dhileepan and advice from the CARG editor, Dr John Carlisle. The researcher contributed the background section, the methodology and developed the search strategies. The researcher and the co-reviewer, Dr Srinivasan Dhileepan, developed the objectives and criteria for considering studies for this review jointly.

The researcher and the co-reviewer, Dr Srinivasan Dhileepan, extracted data from the included studies independently, to ensure accuracy. The researcher conducted the analysis and drafted the review. The co-reviewer, Dr Srinivasan Dhileepan, checked the analysis and commented on the drafts of the review. The third co-reviewer, Professor David Foxcroft, provided support and advice for the process of developing the protocol, conducting and writing the review.

CHAPTER FIVE

METHODOLOGY OF THE INTERRUPTED TIME SERIES

STUDY WITH CONCURRENT WITHIN-PERSON

CONTROLS

5.1 WHAT IS AN INTERRUPTED TIME SERIES?

A time series is a series of observations recorded over time, for example monthly sales figures of a particular product. Time series allows the analysis of these longitudinal data, and the possibility of forecasting future trends based on the observed data. By investigating the nature of the time series and applying statistical techniques it is possible to fit a statistical model to the data, and then predict future values of the variable of interest. In the case of this study, an intervention (the implementation of the early extubation guideline) interrupts the time series, hence the term interrupted time series (ITS).

Data from the year preceding and the year following the implementation of the guideline were collected and key variables, such as time to extubation, were analysed. The first year's data were used to predict the trends for the ensuing three to four months as if the intervention had not happened. This prediction was then compared with the actual data from the second year of the study to assess the effect of the implementation of the protocol.

More commonly used statistical methods assume that the observed data are independent from each other, however observations collected over time may well be related to, or may be dependent on, preceding values (Diggle, 1990). For example, a blood pressure measurement at time point 2 in individual 1 will be related to a preceding blood pressure

measurement at time point 1 taken on the same individual. In the case of early extubation, the point at which a nurse decides to extubate a patient is likely to be related to previous decisions he or she has made. The monthly average times to extubation, for example, may be related to the previous monthly average times because of current views of practice on the unit where the extubation was carried out, the previous experience of the nurses and the knowledge they gain about the practice of extubation.

This dependence of consecutive observations is known as stochastic dependence. In the more familiar ordinary least squares regression model, the stochastic element (the error) is assumed to be normally and independently distributed. With time series analysis the stochastic element is not independent and statistical models have been developed to cope with this type of data e.g. ARMA (autoregressive moving average) and ARIMA (autoregressive integrated moving average) models (Diggle, 1990 and Dattalo, 1998) and . As mentioned earlier, the observations of the time series are not independent of each other and are said to be autocorrelated. The autocorrelation is modelled in the ARMA, or ARIMA models. By using this method of analysis the problem of violating the assumption of independence of observations or measurements required by models such as ordinary least squares regression is overcome.

5.2 WHY USE INTERRUPTED TIME SERIES?

Ideally a randomised control trial of therapeutic interventions would be the design of choice (an experimental design) to assess the efficacy and value of a healthcare intervention. However, it is not always possible to use this research design in the clinical setting for logistical, ethical and financial or resource reasons (Grimshaw et al., 2001b). Using alternative quasi-experimental designs in these circumstances can mean the results are not as reliable or valid. For example, comparing two cross sectional data sets at two

different time points (as is the case with before and after quasi-experimental designs) means it is difficult to control for confounding variables. These confounding variables, or their influence on the results, may be different at the different time points and the results can only be used with caution.

Using time series analysis means trends in the data prior to the intervention can be assessed. A design that is able to detect and assess trends in the data that may confound the effects of the intervention is useful because it will strengthen the conclusions drawn from the study by strengthening the internal validity of the research design. In the case of the current study, it was not possible to conduct a randomised control trial. It would have been virtually impossible to randomise patients and nurses to two groups (the extubation guideline and the control group) and co-ordinate the days the nurses worked with the days on which the patients had their operations.

5.3 RELIABILITY AND VALIDITY

Using controls in an interrupted time series that are not affected by the intervention (implementation of the extubation guideline) further strengthens the internal validity of the design (Grimshaw et al., 2001b). In this study two controls were selected; the number of arterial blood gas samples taken and the colloid fluid balance. Both were measured at 0800 hours on the morning following surgery. These variables were selected because they should not have been affected by the implementation of the extubation guideline. They were also variables about which nurses made decisions. In this study they are referred to as concurrent within person controls.

A threat to validity discussed by Cook and Campbell (1979) is instrumentation. This can occur if there is a change in record keeping during the period under investigation, or a new

way of defining the variable(s) of interest by those keeping the records so it could be reclassified and an effect in the data observed. In order to avoid such pitfalls it is important to pay attention to the definition of constructs and consider the possibility of a change in instrumentation causing an effect in the data. In this study, the operationalisation of constructs has been given careful consideration. Clear definitions of the variables (constructs they measure) are given and the qualitative study gives opportunity to find out, from those involved in the implementation of the guideline, any changes in methods of record keeping. Respondents in the qualitative section of the study identified no changes in methods of record keeping for the variables used in the interrupted time series analysis.

The threat of simple selection has also been addressed (Cook and Campbell, 1979). This threat is where there is a sudden change in the composition in the experimental group at the time of the interruption (implementation of the guideline). Characteristics of the patients in the samples before and after the implementation of the guideline have been analysed to assess their comparability and possible effects on the data (see chapter eight, section 8.1). The selection of the sample has been randomised and inclusion criteria should help to minimise the potential threat of simple selection. The null hypothesis tested was that there were no significant differences between the year one and the year two samples.

Time series can be affected by cyclical influences, such as those resulting from seasonal trends (Diggle, 1990). For example, ice cream sales would probably show an increase during the summer months followed by a decline in the winter. Obviously if the intervention was made at the beginning of summer the series would show a positive effect, but whether it was because of the intervention or just simply the usual series cyclical trend would not be apparent. These sorts of trends can be identified and removed from the time series, as part of the modelling and analysis process. It was not anticipated that there

would be cyclical trends in the data for this study, as cardiac surgery continues throughout the year at an apparently consistent rate at the study site. The data were examined for cyclical trends and none were identified.

Reactivity related threats to construct validity, according to Cook and Campbell (1979) are a problem when the same individual is measured on several occasions over time and if the subjects know when the implementation of the intervention occurred. Neither of these conditions presents a problem in this study, as different individual patients were measured at different time points and none of them knew when the guideline was implemented.

In order to strengthen the construct validity of this study, more than one variable has been selected as an outcome measure for the effect of the guideline implementation. Since standardising the variability in extubation times of different nurses at the research site was one reason the guideline was developed, “time to extubation” has been selected as the key variable of interest. The null hypothesis was that the implementation of guideline did not affect median times to extubation. The median was selected as a measure of average because the monthly data were not normally distributed and the median is not as affected by extreme values as the mean is (Salkind, 2004 and Caulcott, 1992).

According to Hepworth et al (1994), the threat to validity caused by the error rate problem is rare in time series. The error rate problem occurs when there are multiple comparisons among means made. Random heterogeneity of study patients is less likely to occur in studies where there are repeated measures on an individual, because the individual acts as his or her own control. Since measurements are taken on different individuals in the current study, heterogeneity will be assessed by analysing the demographic data, such as comparing the distributions of the samples by age, gender, type of operation and risk

factors for coronary heart disease. The comparability of the samples will be assessed using the chi squared statistic for discrete variables and the t test for continuous variables.

The external validity of a time series is improved by the use of large random samples. In this study the sample is randomised and this strengthens the generalisations that can be made from the results. Replication, as with randomised controlled trials (RCTs) is also a way of making sure the results are reliable. The methods are therefore reported in full to facilitate future replications.

5.4 THE USE OF TIME SERIES IN NURSING AND HEALTH CARE RESEARCH

Time series analysis models are familiar in areas of study such as economics, but are not yet common in nursing research. There has been some interest in using time series analysis for individual case data (Hepworth et al., 1994). These studies differed to the current study because they used repeated measures on individual patients.

Hawton et al. (1999) used time series analysis to look at the effects of a drug overdose in a television drama with rates of presentation in accident and emergency departments for self-poisoning. In this case, different patients were used at different time points, i.e. the numbers of patients treated for self-poisoning were measured at weekly intervals, three weeks before the television programme and three weeks following. A number of centres were used. Statistical models were used, firstly within centres and then across centres. The model used incorporated repeated measures to take into account differences between different centres. Data from many different patients and many centres were combined in this time series analysis. Although the current study was only based at one centre, it is

similar to Hawton et al's study (1999) because data were collected from different individuals at the specified time points.

5.5 HOW INTERRUPTED TIME SERIES WAS USED TO EVALUATE A CLINICAL GUIDELINE IN A CARDIAC SURGICAL INTENSIVE CARE UNIT

The current study investigated the effects of standardising the practice of nurse-led extubation through the introduction of an evidence-based guideline. The guideline was developed by the clinicians at the research site, based on evidence from the literature and from clinical experience. It was in the form of a decision chart (algorithm) to guide the nurses' decision making process regarding the patients' readiness for extubation following cardiac surgery (see Appendix D). How effective the guideline was in reducing the variation in nurses' decision-making processes was measured indirectly by looking at routinely collected patient observations (detailed below as outcome measures, section 5.5.2). Extubation affects patient outcomes directly and these outcomes are, therefore, an indirect measure of the nurses' practice. For example, there may be changes in the average time to extubation (or time ventilated) following the implementation of the guideline. The outcome measure is the length of time the patient was intubated, but it is the nurse who decides how long the patient remains intubated, based on assessment of clinical parameters. Standardising practice using an evidence based clinical guideline should reduce variability in practice among the nurses. This could then reduce extubation times.

Outcomes measured (detailed in the outcomes section 5.5.2) included: time ventilated, time until ready for discharge to High Dependency Unit (HDU- a unit where nurse: patient ratios are less than in Intensive Care Units (ICU), but still significantly higher than on a

general ward, for example one nurse to every two or three patients), hospital length of stay, ventilatory support requirements following extubation (e.g. length of time requiring oxygen therapy of different concentrations and reintubation rates (i.e. reintroducing the breathing tube to resume mechanical ventilation). The outcome measures were routinely collected and kept in the patient notes. The information was transferred by the researcher to a data collection sheet on Microsoft ®Excel (2000) and imported into Minitab (2004) for analysis. Data collection sheets are included in Appendix B.

Other routinely collected clinical data were recorded as part of the study to provide within person controls. These data were not expected to vary as a result of the implementation of the extubation guideline, but might vary as a result of non-specific changes in the unit, e.g. a change in the skill mix of staff on the unit. Two types of routinely collected clinical data were selected as comparative controls. These were management of blood gases and colloid fluid management during ventilation. Blood gas management involves nurses deciding when to take an arterial blood sample from the patient. The sample provides information on blood levels of various chemicals, including oxygen and carbon dioxide. This information is used to guide clinical decisions about how well the patient is being ventilated, or breathing for themselves, and whether a change in intervention is required. Following cardiac surgery, the patient's circulation has been disrupted. The volume of blood in the circulation requires constant monitoring and, in most cases, supplementing. It is part of the nurse's role to administer fluid intravenously, including colloids. In most cases it is the nurses who decide how much colloid fluid to give and when to give it.

The analysis of the number of blood gases taken within a defined period and the amount of fluid required (measured by colloid fluid balance) during this same period, tested for general rather than specific changes in behaviour that are due to factors other than the

intervention (implementation of the guideline). The number of time points selected (12 monthly time points pre implementation and 12 post implementation) reduces the likelihood that a change in colloid fluid management or blood gas management occurs by chance at the same time point when the extubation guideline is introduced. This data provided the within person controls.

The interrupted time series design enables causal inferences to be made, by allowing for the identification of trends over time in the outcome measures. Using the comparative controls enables the comparison of general trends with trends in the outcome measures for the early extubation guideline. Similar trends occurring in both sets of data at the same time points would indicate confounding variables that could account for changes that may otherwise be attributed to the intervention (i.e. the implementation of the guideline).

5.5.1 Clinical areas at the study site

Patients at the study site were nursed in a cardiac intensive care unit (CICU) and they were transferred to a cardiac surgical high dependency unit (CSH DU) once stable after extubation. If a patient's condition deteriorated (for example, if they experienced multi-organ failure), they were usually transferred to the general intensive care unit (ICU).

5.5.2 Sampling

Cook and Campbell (1979) note that different texts on time series analysis suggest different numbers of observations (i.e. number of time points) are required to ensure reliable analysis. They note that 50 observations are often quoted as a sufficient number of time points (e.g. Dattalo (1998), but also that this is not always practical in the research setting. In this study data were collected over a two-year period (24 time points). A key reason for

this is the time constraints posed by completing the study within the three-year period of the programme. Longer time series are useful to help incorporate the effects of seasonal cyclical trends in to the statistical models. There were no seasonal cyclical trends identified in this series, so having more than one year's data before the implementation of the guideline can be argued to be unnecessary. However, the more observations before the implementation, the more monthly predictive forecasts can be made. In this case a year's data have been used to predict three to four months values, which were then compared with the real values from the data collected in the second year. Longer time series also allow more sophisticated time series models to be used, such as ARMA and ARIMA (Dattalo, 1998).

Hepworth et al. (1994) point out that physiological measurements often have a much higher reliability than measures of behaviour. Many of the measurements in the study are physiological, even though they are used to evaluate the impact of the guideline on nurses' behaviour. Therefore a smaller sample (i.e. less than 50 observations) should still provide reliable results.

A random sample of patients for each time point was selected. The sample frame was derived from the research site's database of cardiac surgical patients. The database contained a considerable amount of information irrelevant to the study and so the inclusion and exclusion criteria detailed below were applied to compile a sample frame. A sample of 30 patients for each time point was planned, i.e. 30 patients x 12 months prior to the intervention and 30 patients x 12 months after intervention. In statistics, about 30 cases are generally considered enough to demonstrate a normal distribution (Caulcott, 1992). This improves the accuracy of any inferential statistical tests used on the sample and thus their validity (Caulcott, 1992 and Salkind, 2004).

For each month of the study period (24 months), patients who met the inclusion criteria were allocated a number. Each month's numbers were put into a hat and then 30 numbers, for each of the 24 months, were randomly drawn. However, some months total patient population was less than 30, so all the patients for those months were included in the sample. Once the patients' notes were examined it was evident that some of the information on the database had been entered incorrectly. Some of the randomly selected sample did not actually meet the inclusion criteria. These were excluded from the study at this point and a further random selection of patients was made to replace them. Patients who initially met the inclusion criteria but then had a complicated postoperative recovery requiring admission to a general intensive care unit from the study cardiac intensive care unit were excluded from the analysis. These patients were no longer considered suitable for the early extubation guideline by clinicians and different methods of record keeping between the two units made accurate data collection difficult. A total sample of 567 was achieved; 301 patients for year one and 266 patients for year two.

The inclusion and exclusion criteria used in the sampling process are presented below. A cautious approach to inclusion and exclusion has been taken. This is because the evidence for the effects on postoperative ventilation of some criteria is inconclusive (see chapter 2, section 2.3).

Inclusion criteria:

- **First coronary artery bypass operation.** Patients who had not had any previous coronary artery bypass graft surgery are at less risk of developing postoperative complications than patients having a second or subsequent bypass operation.

- **Elective coronary artery bypass graft patients.** Patients who have coronary artery bypass surgery as urgent in patients or as emergencies could be at greater risk of postoperative complications than elective patients. This is because their preoperative condition is likely to be worse than those admitted electively.

Exclusion criteria:

These variables have been identified in the literature as significant predictors for patients requiring longer ventilation times following cardiac surgery. These variables could therefore confound findings for the effects of implementing the guideline (see chapter two, section 2.3). As the evidence for some is inconclusive a cautious approach has been taken by using some exclusion criteria, such as pre – existing lung disease that may not affect extubation times significantly.

- **Patients who have had previous coronary bypass or valve surgery.** This was because they are at more risk of developing postoperative complications.
- **Patients with poor left ventricular function** (poor pump function of the heart). These patients often require higher levels of cardiac and respiratory support postoperatively.
- **Patients with significant pre-existing lung disease.** This is a variable that may affect respiratory outcomes. In this study it was defined as asthma or chronic obstructive pulmonary disease (COPD) or other lung disease requiring medication for treatment, e.g. inhaled salbutamol and steroids.
- **Inpatient referrals** (patients already in hospital and not well enough to send home prior to surgery)
- **Cardiopulmonary bypass time of more than 120 minutes** (time on the heart lung bypass machine during surgery)

- **Known pulmonary hypertension** (high blood pressure in the lung circulation, reducing the effectiveness of the lungs)

5.5.2 Main outcome measures

- **Time of arrival on unit to extubation.** This measure was chosen because it is the way early extubation is defined in the literature (usually between 6 and 10 hours), with the associated benefits discussed in the literature review. It was chosen to provide descriptive statistics on patients prior to and following the implementation of the guideline, as well as to be used as the key outcome measure for the time series analysis.
- **Time to readiness for transfer to Cardiac Surgical High Dependency Unit (or cardiac intensive care unit (CICU) length of stay).** This was defined as the time of the patient's arrival on CICU until when the patient was ready for transfer to Cardiac Surgical High Dependency Unit (CSHDU). This outcome measure was chosen to indicate the amount of time a patient would need in the intensive care unit, based on clinical need rather than availability of beds or staff in a HDU. Readiness for transfer in this study is defined as respiratory and cardiovascular stability with a stable neurological condition, the ability to protect his or her own airway, alert and responsive and with adequate renal function that was not causing life threatening biochemical imbalance requiring intervention such as haemofiltration. Respiratory stability was indicated by the patient being able to self-ventilate, with arterial blood gas values of $PO_2 \geq 10\text{kpa}$ and $PCO_2 \leq 6.5 - 7\text{kpa}$, with no increasing oxygen demand, a regular respiration rate of less than 30 breaths per minute. Cardiovascular stability was indicated by a stable arterial blood pressure with or without low dose inotropic support (e.g. epinephrine or norepinephrine $\leq 0.06\text{ mcg.kg.min}$), no increasing need for

inotropic support, no life threatening dysrhythmias (e.g. ventricular fibrillation, ventricular tachycardia) and at least two hours of $\leq 100\text{mls/hr}$ of drainage from the chest drains.

- **Time (in days) to discharge from hospital (or hospital length of stay).**

One of the benefits of early extubation is considered to be earlier discharge, so any trends in average hospital length of stay may have been affected by the extubation guideline.

- **30-day readmission rates.** The researcher planned to collect data on readmission rates and the reasons for readmission. Unfortunately, the available data were too incomplete for a meaningful analysis. The research site was a tertiary referral centre and many patients may have been readmitted to their referring hospitals and the researcher did not have access to this information.

- **Time to patient being self-ventilating on 40% oxygen with oxygen saturations $\geq 95\%$.** This outcome was selected to assess the length of time it took patients to have resumed self-ventilation and were demonstrating a good recovery by a reducing oxygen demand. If the patient's oxygen saturations are not recorded as being $\geq 95\%$ on 40% oxygen, the time at which the patient's oxygen requirement was recorded as 2 litres or less was be used. (The use of litres is how oxygen delivery was recorded when delivered via nasal cannula or a face mask without valves to deliver specific percentages of oxygen). This will be used as an indication that the medical team considered the patient's oxygen levels to be adequate for that patient. This is not a usual measure in studies on early extubation (see literature review, chapter two for more usual variables).

However, it was selected to show progress in recovering preoperative respiratory function. Oxygen demand can be affected by many factors that may be complications of cardiac surgery such as chest infections and pulmonary oedema and it was anticipated that these complications would be similar in both samples. If there were any differences between the years, it may have been due to the implementation of the early extubation guideline.

- **Reintubation rates.** This outcome is a key indicator for the failure of extubation. Although the results of this analysis are presented in chapter eight, section 8.1.3, the incidence of reintubation was low and the results should be treated with caution.
- **Reasons for reintubation.** Reasons were classified under two subsections: respiratory and cardiovascular. The reasons for reintubation are important, because in order to assess whether a patient was extubated too early and went into respiratory failure, one needs to exclude reasons for reintubation, which were not the result of respiratory failure, such as a need for re-operation.
- **Use of facial Continuous Positive Airway Pressure (CPAP-** a non invasive mode of respiratory support).

This outcome measure was chosen as CPAP is a method of respiratory support often used when a patient is showing signs of respiratory failure and it is often used to try and prevent reintubation. The reasons for use of CPAP were also recorded to assess how successful the early extubation was. The incidence of needing CPAP was low, so an analysis of the reasons for needing CPAP was not conducted, because the results would not be meaningful.

5.5.4 Data analysis

The data were analysed to provide demographic and descriptive information. These data were used to assess the similarity of the samples from the first and second year of the study. The variables that were examined were chosen because they could affect the outcomes of surgery and time needed for postoperative ventilation. The discrete variables were divided into preoperative, operative and postoperative variables and chi square was used to test for significant differences in the samples. The continuous variables were tested using the t test.

Preoperative variables:

Gender

Age

Previous myocardial infarction (MI)

Hypertension: defined as a systolic pressure of >140 or a diastolic pressure of >90 (World Health Organisation/International Society of Hypertension, 1999), or by admitting clinician recording the patient as hypertensive.

Hypercholesterolaemia: defined as a total cholesterol of >5mmol/l (British Cardiac Society, British Hyperlipidaemia Association and British Hypertension Society, 1998), or by admitting clinician recording the patient as hypercholesterolaemic.

Smoking; three groups were identified: current smokers, ex-smokers who had given up for 6 months or more and those who had never smoked.

Diabetes (either type I or type II)

Previous rheumatic fever

Previous transischæmic attack (TIA)

Previous cerebrovasucular accident (CVA)

Previous deep vein thrombosis (DVT)

Peripheral vascular disease (PVD)

Left ventricular (LV) function: moderate was defined as having an ejection fraction (EF) of 20-40% and good as having an EF of more than 40%

Chronic renal failure – defined as having a preoperative createnine of greater than 150 mmols/litre

Type of coronary heart disease, i.e. one vessel, two vessel or three vessel disease.

Operative variables:

Surgeon performing the operation – different surgeons may have different techniques that could affect the outcomes

Anaesthetist –different anaesthetists could use different anaesthetics during surgery that could also affect the outcomes

Whether the surgery was on cardiopulmonary bypass or off cardiopulmonary bypass – the use of cardiopulmonary bypass or not could affect the outcomes. The different techniques could account for differences in the outcomes if the rates of each technique were different in each year.

Postoperative variables

Reintubation rates

Primary reason for reintubation: either respiratory, cardiovascular or a combination of the two

Need for continuous positive airway pressure (CPAP) post extubation

In hospital death

The outcome measures time to extubation, time to transfer to CSHDU, time until self-ventilating on 40% oxygen, time needing the use of CPAP and time to discharge from hospital were also used to compare the samples from each of the two years. The median was used as a measure of average because it is less prone to being affected by extreme values than the mean, particularly if these extreme values skew the distribution of the sample (Caulcott, 1992 and Salkind, 2004). With cardiac surgery patients, complications for one patient can cause them to need a much greater time of ventilation than is usual for an uncomplicated recovery. Therefore, one patient's ventilation time can significantly affect the mean. The median is more useful to clinicians because it is not so affected by a small minority of patients' results that are extreme.

The within person control variables (colloid fluid balance and number of arterial blood gas samples taken) are presented as mean values for each year. The mean was chosen for these variables because the number of arterial blood gases or the amount of fluids given were time limited for all patients and would therefore be unlikely to have been so affected by extreme outliers as the previously discussed variables (i.e. the distribution of the sample was at less risk of being skewed). They were normally distributed and so the mean was an appropriate measure of central tendency for the samples (Salkind, 2004). The comparability of the samples was tested with the t test.

In order to make sure the assumptions about whether to use the median or the mean to present the results were correct, the distributions of all the variables discussed above were assessed to see if they were normally distributed or had skewed distributions. The results

presented in chapter eight are based on these evaluations with the mean being used for normally distributed variables and the median for variables with a skewed distribution.

Time series modelling was used for the following outcomes:

Time to extubation

Time until self-ventilating on 40% oxygen

Time to readiness for transfer to CSHDU (or CICU length of stay)

Time to discharge from hospital (or hospital length of stay)

It was planned to use the variable need for CPAP post extubation for the time series analysis, however the incidence of patients needing CPAP was too low to enable a monthly average to be accurately modelled.

A statistical model was applied to the data and assessed for fit. The best fitting model for each variable was used to predict the first four months values of the second year if the guideline had not been implemented using the first year's data. The second year's data were also modelled and a comparison made between the predicted and actual values. The null hypothesis that there was no difference between the predicted values and the actual values was assessed by considering whether the actual values fell within or outside the confidence interval for the predicted values. If the actual values fell within the confidence interval of the predicted values there was no significant difference between the predicted values and actual values. This would mean the null hypothesis that the implementation of the early extubation guideline did not affect the study outcomes could not be rejected. The null hypotheses for each individual outcomes used in the interrupted time series analysis are as follows:

The implementation of the early extubation guideline did not affect the time to extubation.

The implementation of the early extubation guidelines did not affect the time until patients were self- ventilating on 40% oxygen

The implementation of the early extubation guidelines did not affect patient's CICU length of stay

The implementation of the early extubation guidelines did not affect patients' hospital length of stay

The statistical computer package MiniTab (2004) was used to analyse the data.

Time series analysis follows several stages starting with a descriptive stage. The time series was plotted in order to identify any trends, cyclical fluctuations or seasonal fluctuations. Any trends were identified and were extracted from the series, leaving a series of residuals. These residuals or irregularities may be caused by random variables and can be modelled to provide explanation. The irregularities sometimes need smoothing before they can be used to forecast future values. This was the case with this study.

Exponential smoothing was used for the time series after seeking statistical advice.

Exponential smoothing can be single exponential or double exponential. These models use a weighted average of past and present values to smooth the current value. The mean square error (MSE) is used to optimise the weight used for smoothing. MiniTab (2004) was set to set automatically the smoothing constant in this analysis. The MSE was also used to assess the fit of the model. The lower the value of the MSE (MSD in MiniTab (2004) the better the fit.

The time series used for forecasting values into the second year of the study, as if the guideline had not been implemented, consisted of 12 observations. This was due to the time constraints of the PhD programme. About 50 observations (i.e. 50 different time points) are recommended for validity of ARMA or ARIMA models (Dattalo, 1998 and Cook and Campbell, 1979). As this study only had 12 observations prior to the intervention it was not possible to proceed further with the time series analysis and use the more sophisticated ARMA or ARIMA. These models aim to explain the structure of the stochastic processes of the time series. However, it was still possible to use the exponentially smoothed time series to make forecasts and compare these forecasts with the actual values collected in the data from the second year of the study.

CHAPTER SIX

METHODOLOGY OF THE QUALITATIVE STUDY –

INTERVIEWS DRAWING FROM APPLIED

PRACTITIONER ETHNOGRAPHY

6.1 INTRODUCTION

In order to gain insight into possible reasons for the results of the interrupted time series study and to explore reasons contributing to a successful clinical guideline implementation, a qualitative study of the process of developing and implementing the early extubation guideline was conducted. This qualitative study draws on principles from applied practitioner ethnography, in a subtle realist framework (Hammersley, 1992). Data collection methods were interviews and a reflective diary kept by the researcher. The interviews were conducted with all the staff involved in the development and implementation of the guideline and a purposive sample of staff that used it. The reflective diary was used to facilitate reflexivity in the research. It focused on the researcher's impact on the development and implementation of the guideline and her impact on the research.

A thematic content analysis (detailed section 6.4 and the results presented in chapter nine) of the interview data and the researcher's reflective diary data provides detailed information on the intervention of implementing a clinical guideline for early extubation of adult cardiac surgery patients. The conclusions drawn from this analysis may also inform other similar practice development initiatives. There is no such qualitative research currently published on the implementation of a nurse-led extubation guideline in cardiac surgery. This section of the study therefore, also provides unique research evidence.

6.2 WHY QUALITATIVE INTERVIEWS DRAWING FROM APPLIED PRACTITIONER ETHNOGRAPHY?

The qualitative interviews were conceived as part of the whole evaluation study and were selected as a method of data collection to gain an in-depth understanding of the process of the development and implementation of the early extubation guideline. It was hoped the data would provide some explanation for the results of the interrupted time series. Although not a pure or full ethnography, the current study drew on applied practitioner ethnography in the subtle realist tradition (Hammersely, 1992) which provides this section with a philosophical and conceptual framework.

The applied practitioner ethnographic stance was selected because this part of the study was conceived as an exploration of the meanings the participants gave to the social processes involved in the guideline development and implementation. Ethnography is a methodology and a set of methods used in qualitative research to study social phenomena in their natural settings in order to describe, explain or theorise about the phenomena under investigation (Brewer, 2000 and Pole and Morrison, 2003). It also give importance to the meanings and actions of the actors (or participants) in the research setting, to study these social phenomena (Pole and Morrison, 2003). Using ethnography to study a particular part of a culture is often termed applied ethnography rather than a pure ethnography (Brewer, 2000).

Pure ethnography aims to understand the patterns of life and relationships within a whole culture. Pole and Morrison (2003) suggest five common principal characteristics of ethnography. Firstly ethnography focuses on a discrete location, event(s) or setting – in this case the setting was a cardiothoracic intensive care unit and the events were those connected with the implementation of the extubation guideline.

Secondly, ethnography is usually concerned with the full range of social behaviour at the setting. The current study differs from this, in that it was particularly focused on participants' reports of the events surrounding the guideline development and implementation. Applied ethnography (discussed below) allows for a more specific focus. The decision to use only interviews, in the context of the mixed methods approach, also accounts for the different focus of the current study. Thirdly, ethnography uses a variety of research methods to understand social behaviour from the inside of the research setting. This study was limited to two methods of data collection. However they were chosen to explore insiders' understandings of the guideline development and implementation. Fourthly, data analysis moves from description to identifying concepts and theories. This study follows this analytic process, although not going as far as theorising. Fifthly, ethnography is rigorous and usually gives more importance to the complexities of the setting, events or location than to general trends. Because the process of implementing the guideline was complex, ethnography offered a possible way of exploring some of this complexity. The rigour often associated with ethnography, was limited in this study because of the chosen approach to data collection. This also means the current study is more limited in its exploration of complexity than had it been a pure, full ethnography.

Pure ethnography is sometimes referred to as 'macro-ethnography', in contrast to 'micro-ethnography' (applied ethnography), which is a study of a particular aspect of a culture (De Laine, 1997 and Roper and Shapira, 2000). Chambers (2000) suggests, ethnographic approaches to research are often found in clinical research and they can be regarded as applied ethnography. Applied ethnography is frequently used for policy relevant research in areas such as education and health. It has been used in evaluative research, where evidence about the effectiveness of an intervention is sought from the perspectives and experience of the people concerned (Brewer, 2000), as is the case with the current study.

Mixed methods approaches to studying a particular topic can also use applied ethnography (De Laine, 1997). This was also the case with the current study.

Applied ethnography, therefore, is a suitable approach to inform this part of the study because it was investigating an aspect of the clinical culture at the research site, in order to offer explanations of the processes involved and their impact on the results of the interrupted time series. The whole investigation could have been conducted as an ethnography, rather than using a mixed methods approach. The mixed methods approach, however, facilitated the aims to quantify the impact of the guideline implementation on patient outcomes, to seek an explanation for the findings of the interrupted time series and to gain insight into the process of developing and implementing the guideline at the research site. A completely applied ethnographic study would have been more suitable if the aim of the research had been to explore the culture and its structures at the research site. These might have been revealed in the process of developing and implementing the guideline.

In ethnography, the researcher usually gains access to all forms of the data by developing relationships with the participants, through prolonged periods of engagement in the setting. This engagement is usually achieved through participant observation (Lutz, 1989, Hammersley, 1992, Hammersley and Atkinson, 1995 and Brewer, 2000). Although participant observation was not used in this study, the researcher was a member of the setting where the research was conducted and so had an insider's perspective.

One of the main reasons for using participant observation in ethnography is to gain as near as possible an insiders' understanding of the setting, to develop an understanding of the culture that informs their observations (Hammersley, 1992, Hammersley and Atkinson 1995

and Brewer, 2000). The researcher, in this study, had an insider's knowledge of the culture of the study setting because she worked there. The researcher used her knowledge of the research site to identify key respondents for the qualitative interviews and her implicit understanding of the site and existing relationships facilitated this access (see chapter 9, section 9.8.1a and 9.8.b for themes related to the researchers reflections on this aspect of her knowledge of the research site). The researcher also felt she already had a rapport with the respondents, from working with them. An outsider would take a considerable amount of time to establish this kind of understanding of the site and it would be part of their participant observation.

The process of a stranger learning the new culture gives the researcher an ability to stand back and observe it in a way that is difficult for insiders to do, because insiders may not be consciously aware of the presuppositions they have about their view of their setting (Hammersley and Atkinson, 1995). Although the researcher was an insider, she had not always been part of the research site and had had to learn the culture. She could access reflections on that learning process and she was not as much an insider as someone who had been born into a particular culture. The researcher could use the experience of learning the culture when she started working there to aide her ability to stand back in order to try to understand other insiders' (i.e. the participants who were interviewed) views. This did not mean it was not a challenge to make her cultural presuppositions conscious and the reflective diary provided data on this process (see chapter nine, section 9.8).

Tedlock (2000) suggests that a researcher researching in his or her own culture has been a feature of ethnographic research since the 1930s. Hammersley (1992) also discusses the type of research he terms 'practitioner ethnography'. Practitioner ethnography involves practitioners researching their own settings to discover information pertinent to practice

issues, as was the case with this study. Hammersley (1992) suggests that an advantage of this type of ethnography is its potential for relevance to practice and policy. He suggests that the insider's existing knowledge of the setting is advantageous compared to an outside researcher who will have to spend a long time in the setting to gain similar knowledge. The kind of knowledge includes the history of the setting, having existing relationships with others in the setting, having direct access to their own motivations, although these interpretations can still be erroneous, and having direct access to the setting gives practitioner researchers the opportunity to test their theories in a different way from an outsider.

Clearly, there may be some advantages to being a practitioner ethnographer. However, an outside researcher may not have as many constraints or dilemmas to overcome, such as not having relationships with all those that contribute to the setting or the phenomenon under investigation, or that a practitioner's access to the site and their perceptions come from the practice role they hold. This practice role may also limit access to some types of information. Hammersley (1992) concludes that practitioners are unlikely to have access to knowledge that an outsider would not and that, although the different approaches have advantages and disadvantages, there is no clear indication that one is better than the other. Because the researcher was also a clinician at the research site, this research draws on the tradition of practitioner ethnography discussed by Hammersley (1992). The reflective diary was used to collect data on how the researcher considered her dual role as a clinician and a researcher impacted on the process of developing and implementing the guideline and on the research itself. Participants were also asked for their views of the researcher and clinician roles to provide triangulation of data on this subject.

Although the qualitative part of this study is not intended to be a full, applied practitioner ethnography, the philosophical basis of and the methods used in it, however, draw from this type ethnography. These issues are explored in more depth below.

6.3 WHAT IS THE PHILOSOPHICAL BASIS FOR A STUDY DRAWING FROM APPLIED PRACTITIONER ETHNOGRAPHY?

Ethnography is a social research methodology, which traces its roots to anthropology, and uses a particular set of research methods. Social phenomena in their natural settings, rather than under experimental conditions are studied in ethnography (Pole and Morrison, 2003). There is a variety of approaches to and descriptions of ethnography and some suggest its characteristics are best identified by a particular set of methods, of which participant observation is perhaps the most characteristic (Hammersley and Atkinson, 1995 and Hammersley, 1998). The researcher, who aims to be as close to the setting as possible, observes the participants' (i.e. the people in those settings) meanings and actions. This most often involves the researcher's direct participation in the setting (participant observation) (Brewer, 2000). Participant observation was not used and this is a significant difference between the current mixed methods study and a full ethnography. However, it does not mean understanding the participants' views and meanings about the guideline development and implementation could not be accessed through the chosen methods of data collection.

Hammersley and Atkinson, (1995) suggest that ethnography is not particularly distinct from other forms of qualitative research because all social researchers are participant observers in some way. This is because they are inseparably part of their social worlds. Brewer (2000) argues that method and methodology are intertwined in ethnography and that it should not simply be defined as a set of data collection procedures. He discusses

how methodologies are the broad theoretical and philosophical frameworks that the methods fit within. It is these philosophical and theoretical perspectives that influence the methods of data collection that are used. Brewer (2000) points out that the application of the methods is what is usually criticised in poor quality research rather than the philosophical and theoretical framework used.

Ethnography has undergone a substantial critique of its philosophical and theoretical positions in recent decades. Ethnography had a tradition in two philosophical camps; naturalism, particularly from a humanistic perspective; and positivism (Hammersley, 1992, Hammersley and Atkinson, 1995 and Brewer, 2000). The naturalistic view suggests that social life cannot be broken down into cause and effect relationships, as suggested by a positivistic view of the world. Naturalism considers that research methods facilitating close observation in the natural setting, rather than under experimental conditions will provide a revelation of an objective truth about the nature of one or more particular social phenomena (Hammersley, 1992 and 1998). Naturalism also includes the idea that humans have the ability to interpret and construct their social worlds. This includes the premise that people's meanings are part of the social world and these meanings should be accessed as part of obtaining a complete picture of the phenomena under investigation (Brewer, 2000 and Pole and Morrison, 2003).

The positivist idea of identifying causal relationships, in the sense of breaking phenomena down into constituent pieces and determining the cause and effect relationships between these pieces, is therefore problematic for naturalistic ethnographers because research is incomplete if peoples' meanings and interpretations are not taken into consideration. The best way of gaining understanding and insight into the social world is, therefore, to study

and represent it in real settings from the closest perspective possible, that of an insider.

The research needs to be inductive rather than deductive.

Ethnographers who were influenced by positivism took the view that, if their methods of research were rigorous and scientific, then ethnography could be regarded as reliable and valid in positivist terms. They too considered that social settings held an objective truth that could be revealed through rigorous ethnographic study. This included a view that the influence of the researcher on the research and its interpretation could be minimised, just as methods of data collection sought to do in the positivist tradition of research. The resulting account of the research could therefore be objective, revealing the 'truth' of the social phenomena under study (Hammersley, 1992, Hammersley and Atkinson, 1995, Denzin, 1997 and Brewer, 2000).

The more recent influences of postmodernism's and of post-structuralism's deconstruction of reality have provided both positivist and naturalistic ethnographers with a critique of their methodology (Hammersley and Atkinson, 1995 and Denzin, 1997). According to Hammersley (1992), Hammersley and Atkinson (1995) and Brewer (2000), fundamental to this critique is the question of what reality is and whether it can be known. Denzin (1997) suggests that two of the areas the debate has caused a 'crisis' for ethnographers are in how ethnographers represent their data and how ethnographies should be evaluated.

The discussion of representation suggests that the narrative production that results in ethnographic writing used to be seen as a representation of reality. However, according to Denzin (1997), the post-structural critique suggests that language and speech, the basis of ethnographic data, are not exact representations of experience, but rather creations of experience. These creations involve changing meanings as respondents tell their stories.

Ethnographic narratives cannot, therefore, be exact reflections of reality, but only representations of what has been meant or said. The issue of evaluation is discussed further in section 6.5 on reliability and validity.

Similarly, Hammersley (1992) considers that both naturalistic and positivistic ethnography had a naïve view of the reality of social phenomena. They both included the premise that the reality of the social phenomena under study could be directly accessed through ethnographic research. He terms this 'naïve realism'. Hammersley (1992) suggests that, rather than abandoning all possibility of identifying, understanding and explaining social phenomena and accepting the argument of relativism, that there are as many perspectives of social phenomena as there are people, ethnographers can have a more sophisticated view of an independent reality in their investigations. He terms this view of reality as 'subtle realism'.

Both subtle realism and naïve realism consider that independent and knowable features of social phenomena exist. However, the important difference is that unlike naïve realism, subtle realism suggests that these features cannot be accessed directly. These features are always viewed through the researcher's own cultural assumptions, just as they are for each of the participants of the research setting. Subtle realism incorporates an acceptance of the idea that knowledge is socially constructed but it also recognises that there are features of the social phenomena that are independent of the researcher, and indeed the actual members of the social setting (Hammersley, 1992 and Brewer 2000).

There is a need, then, to assess the impact of these cultural assumptions, from the participants' accounts and the researcher's accounts and interpretations, on the research.

Hammersley (1992) suggests that triangulation of data can be used to assess the

constructions and cultural assumptions implicit in participant's accounts and actions.

Reflexivity is the term used to describe this aspect of ethnographic research (Hammersley, 1992, Hammersley and Atkinson, 1995, Denzin, 1997, Aull Davies, 1999, Brewer, 2000, Sherman Heyl, 2001 and Pole and Morrison, 2003), and has gained importance in the practice of post-modern ethnography. Reflexivity, on the part of the researcher, is seen as a way of making explicit and assessing the impact of their own cultural assumptions on the research. This impact can be related to the researcher's cultural assumptions (Hammersley, 1992), their interpretation of the data (Aull Davies, 1999) or their involvement in the construction of the data. For example, the way the researcher interacts with the research participants helps to construct the data (Denzin, 1997 and Aull Davies, 1999).

Aull Davies (1999) suggests that when reflexivity is taken to post-modern extremes, it can lead to the conclusion that there are only individual perspectives of a society's culture. This, as Hammersley (1992) suggests, leads to equating ethnography with journalism, or, as Aull Davies suggests (1999) it can be seen as revealing more about the ethnographer than the societies they study.

Like Hammersley (1992), Aull Davies (1999) suggests some alternative approaches to an introspective post-modern view of ethnography. One approach has been to raise participants' perspectives to an equal status as that of the researcher by the use of such techniques as long narratives or participants being given the opportunity to comment on the ethnographic texts that involve them. Another response, favoured by Aull Davies (1999), is a realist alternative for the philosophical basis of ethnography and is termed critical realism.

A critical realist approach to ethnography is an attempt to integrate the positivist understanding of an independent reality that can be known with the more hermeneutical views of social research and, in particular, the interpretivist tradition in ethnography. This view of ethnography supports the idea it can provide explanations, and not simply descriptions, that can be applied beyond the research. At the same time, ethnography can also offer hermeneutic insights into the phenomenon under investigation and incorporate the reflexive understanding of the researcher's impact on the study (Porter 1995 and Aull Davies, 1999).

Acknowledging the work of Roy Bhaskar, Porter (1995) and Aull Davies (1999) point out that underpinning this view of ethnography, is a subtle and complex view of society, where actors (participants) are seen neither as simply passive products of society nor as entirely creating their social structures. It offers a view of society as independent of an actor's conceptions of it, where society can influence the actors but they can also influence it, because society is dependent on actors' actions for its reproduction. Society and its continued existence are seen as an iterative process. Aull Davies (1999) suggests that ethnography using this critical realist philosophical basis and view of society can integrate both positivist and naturalistic values. As a result, ethnography can offer explanatory statements that are rooted in specific times and places, and not simply descriptions or individual perspectives of phenomena (Aull Davies, 1999).

There are some important similarities between Hammersley's (1992) subtle realism and critical realism, outlined by Aull Davies (1999), that give a theoretical and philosophical basis for the current study's choice of interviews using an ethnographic stance. They both consider that there are independent features of social phenomena that can be known, but that the participants and the researcher view these through their own cultural assumptions.

The researcher and the participants can also affect these social phenomena and structures through their participation in the research setting, i.e. they construct the data through interaction, but the data contains perspectives of the independent truth. Reflexivity is a key feature in this type of ethnography, through the researcher's attempt to assess their impact on the phenomenon under investigation.

According to Porter (1995), a main difference between subtle realism and critical realism lies in how the different perspectives are evaluated. Subtle realism focuses on understanding the perspectives rather than judging them. Critical realism, however, seeks to evaluate critically the perspectives. This inevitably means the researcher uses judgements, which can be considered moral. That is, the critical evaluation involves judging the effects of the identified social structures on human thought and action.

Understanding perspectives of the guideline development and implementation was the focus of the current study. Using this understanding to help offer explanations of the results of the interrupted time series was another aim. These two aims, therefore, led to a subtle realist view of data interpretation.

The aim of the qualitative study interviews, drawing from principals of applied practitioner ethnography, was to identify the independent features of the process of development and implementation of the guideline and offer explanations of the process and the results of the interrupted time series analysis. This was achieved by using interviews to investigate participants' perspectives, identifying their interpretations and constructions of the social phenomenon of the development and implementation of the early extubation guideline. Reflexivity was also a feature of this research using triangulation, although limited, of data from different participants and the researchers' reflective diary. The data provided different perspectives and interpretations of the development and implementation process.

These data were used to develop a representation of the process that might explain the results of the interrupted time series and some insights into broader issues surrounding the implementation of guidelines in clinical practice.

6.4 FEATURES OF ETHNOGRAPHIC METHODS AND THEIR APPLICATION TO THE QUALITATIVE STUDY

6.4.1 Identifying a research question in ethnography

The qualitative study was conceived as part of the mixed methods approach rather than evolving through a full ethnography. The qualitative part of the study was designed to help explore the meaning of results from the quantitative interrupted time series and explore the process of the guideline development and implementation. In contrast, the focus for the research question in a complete ethnography would be gradually identified, explored and refined through fieldwork (Hammersley and Atkinson, 1995). However, in spite of the research question being developed before the study was conducted, the research question's development was influenced by the researchers' participation as a clinician in the research site prior to the study. Therefore, although the question was not intentionally developed as part of a full ethnography, the researcher's reflections on practice in her role as a clinician significantly contributed to the study question. These reflections resulted in a category, effects on research design, in the theme *implicit knowledge* emerging from the data (see chapter nine, section 9.8.1).

6.4.2 Data Collection

Ethnography can use various methods of data collection. Data collection is often, but not always, facilitated by participant observation (Brewer, 2000). Ethnography can involve several methods of data collection; otherwise, triangulation would not be possible.

Characteristic methods of data collection include field notes of observations, in-depth interviews that can be formal or informal, use of documents, mapping, life histories or videos (Hammersley, 1992, Hammersley, 1998 and Brewer, 2001). These methods are familiar in other qualitative research methodologies, but their use in ethnography is characterised by the flexible way they are used, as well as the philosophical stance of the researcher.

Ethnography is an exploration of a culture with the study gradually evolving. One section of data collection may lead to others as interesting leads are discovered and followed up. The analysis of data during the fieldwork helps with this process of discovery, by enabling the researcher to identify areas or issues for further investigation. The investigation may proceed by exploring new areas or by searching out further data on a particular issue that has emerged, in order to establish its significance and all its features (Hammersley, 1995 and Brewer, 2001).

The current qualitative study was distinctly different to this evolving exploration, which is characteristic of a full ethnography. The flexibility suggested as a feature of ethnography above, was clearly not a main characteristic of this study. It was limited by the researcher's decision to use only two methods of data collection (interviews and the researcher's reflective diary) and to explore a specific issue rather than allowing issues to emerge from the data. However, the approach taken in this study fits with the tradition of applied ethnographic research where the features of a culture can be explored by focusing on a particular event or phenomenon occurring in a culture to see what it reveals about the culture as a whole (see section 6.2). The limits chosen for types of data collection were also determined by the qualitative study being only one part of a mixed methods evaluation study.

6.4.2a Development of the interview schedule

The qualitative interviews were semi-structured. This allowed certain topics, such as the dual role of the researcher and clinician, to be explored, but it also allowed for other topics that emerged from the interview process. The topics on the interview schedule (see Appendix B) were developed by considering the aims of the study and considering how to explore process of a guideline development and implementation project. For example, insight into the results of the interrupted time series was sought by asking the respondents their views of the process. In particular, by asking what was involved in developing and implementing the guideline, identifying what went well and what was challenging gave respondents the opportunity to give their views and interpretation of the process. The researcher considered the broad features of a practice development project, which resulted in the topic areas such as setting aims and objectives, exploring how the project progressed, as well as its impact. The researcher's inside knowledge of the guideline development process also informed the selection of topics for the interview schedule, for example what the interviewees had learnt through the process.

The questions were deliberately kept broad so that respondents' perspectives of issues could emerge, rather than being guided very specifically. The researcher wanted to let the participants' views drive the data rather than trying to explore issues that have been identified in other guideline implementation research studies. This resulted in a decision not to use the literature to develop very specific questions about guideline development and implementation. However, the researcher felt it was essential, in light of this decision, to discuss the findings in relation to existing literature (see chapter 12). The choice to keep the topics broad and general, but also focus on the progress and process of the guideline development implementation, was also partly due to the evaluative nature of the study.

That is, the researcher wanted to make sure there was opportunity to explain or explore reasons for the interrupted time series results, a primary aim of the qualitative study.

The interviews inevitably involved the researcher asking supplementary questions to facilitate expansion of the topic discussed or for clarity. The interview schedule could, therefore, be considered a prompt for the researcher to cover topics she felt were relevant to finding explanations for the interrupted time series as well as to explore the guideline development and implementation process. At the same time, the interviews were flexible enough to facilitate exploration of other topics raised by the respondents.

This description of the interview process is an example of how the researcher and the respondent co-create or construct data (see above discussion in section 6.3). Although the researcher tried to keep her own views of the topics discussed to herself during the interviews, to give more importance to the respondents' perspectives, her influence on the content of the interview is clear in the way topics were selected for the interview schedule.

The development of the interview schedule and its topics owes more to evaluation research than to ethnographic interviewing. Its development is clearly linked to the use of a multi-method approach to explore a particular topic from different angles (evaluation research) rather than interviews evolving and developing from the fieldwork to help define areas for further exploration, as would often be the case in pure ethnography.

6.4.2b Sample Selection

The respondents were selected to give different perspectives of the development and implementation of the guideline and its use in practice. In ethnography, the process of identifying respondents is often facilitated by participant observation, which was not part of

this study. The prolonged engagement in the research setting through participant observation could help the researcher identify key informants, or people who could allow access to such informants (Hammersley and Atkinson, 1995). However, in spite of not using participant observation, gaining access to respondents was made relatively easy, in this study, because the researcher was a researcher practitioner (Hammersley, 1992, see discussion in section 6.4.2). She knew who was involved in the guideline project, who the managers and what their roles were. She also knew the staff using the guideline. The researcher used her inside knowledge of the research site to identify key respondents.

The selection of respondents was designed to gain as many views from the project team as possible and to gain a broad range of views from nurses who used the guideline. All those involved in the development and or the implementation teams were interviewed, as were managers, who oversaw the project. The project team consisted of nurse managers and clinical nurses grades G – D and an anaesthetist. It was lead by a clinical nurse, rather than one of the managers. At least one nurse from each clinical grade, who had not been involved in the project team, was selected to give their views of using the guideline and the implementation process. The range of grades was designed to gain views from nurses with different amounts of clinical experience. The interview sample consisted of:

- Four senior clinicians with managerial responsibilities covering the management of medical staff and nursing staff to clinical specialist and practice development duties.
- Seven nurses from clinical grades G to D (sisters to junior nurses).

Of the eleven participants, four were nurses who used the guideline and seven were members of the project team or managers. In order to protect the participants' identities, no more specific information is given in the analysis as to their positions or roles in the implementation, unless more than one participant from a similar position expressed a

similar view. For the same reason, only the broad staff grouping the respondent belonged to, that is, staff or project team identifies quotations. Participants are also referred to as respondents in chapter nine, as their data was collected in interviews where their role was that of a respondent.

6.4.3 Data Analysis

The analysis of ethnographic data from the different sources followed up during fieldwork leads to the 'thick-description' that is a distinctive feature of ethnography. Ethnographic accounts are usually full of data extracts that illustrate observations or points made. There are different way of analysing ethnographic data that range from predominantly descriptive, attempting to 'tell it like it is' from the participants view points, through explanatory accounts to those that build or develop theory (Hammersley, 1992 and Brewer, 2001). Hammersley (1979) suggests that these different types of analysis relate to different levels of abstraction. That is, beyond the narrative or purely descriptive level, the categories of analysis may become more and more abstract. The categories may range from: explaining the meanings from particular situations to moving beyond the research setting to apply to general similar situations in other settings. This last type of analysis is considered theoretical. In this study, the aim was to look for explanations as well as describe the process of developing and implementing the guideline.

Brewer (2001, p.109) identifies a number of steps in the analysis stage:

- Data management (organising the data into manageable units)
- Coding (indexing the data into categories and themes)
- Content analysis
- Qualitative description (identifying the key events, people, behaviours, providing vignettes and appropriate forms of counting)

- Establishing patterns in the data (looking for recurring themes, relationships between the data)
- Developing a classification system of open codes (looking for typologies, taxonomies and classification schemata which order and explain the data)
- Examining negative case (explaining the exceptions and the things that do not fit the analysis).

These steps are not meant to be prescriptive and not all ethnographers use all of them. The steps followed depend on their appropriateness to the purpose of the research. There are, therefore, many different approaches taken by ethnographers to data analysis (Hammersley and Atkinson, 1995 and Brewer, 2001). Clearly, ethnographies that seek to develop explanations about the social features they describe, or to go further and develop theory will follow through the majority of these steps. The level to which the analysis goes is equated with the level of abstraction of the categories used. If the ethnographer is attempting to abstract their findings to find patterns or themes and apply beyond the research setting then they could be considered to be theorising (Hammersley, 1979).

This qualitative study aimed to find explanation and particularly focused on a content analysis of the data that used coding and identifying themes (Brewer, 2000). The data analysis was structured using the Framework approach (Ritchie, 1994). This approach is described in more detail in section 6.4.4. The themes from the data analysis were then used to find explanations for the results of the interrupted time series. The themes were also compared and contrasted with existing literature on guideline implementation (see chapter twelve).

6.4.4 The Data Analysis Process

A thematic content analysis of the qualitative data was conducted using the 'Framework' approach developed by an independent social research institute, Social and Community Planning Research and described by Ritchie and Spencer (1994). There were five stages in the analysis process: familiarization, identifying a thematic framework, indexing, charting and mapping and interpretation.

6.4.4a Familiarization

During this first stage, the researcher read through the transcripts and listened to tape recordings of all the interviews. The purpose of this stage was to become familiar with the content and range of topics and views contained in the data. The researcher noted themes that seemed to recur either related to the questions on the interview schedule or themes that were raised by the respondents.

6.4.4b Identifying a thematic framework

The researcher developed a thematic framework from the notes made during the familiarisation stage. The framework, or index, consisted of important issues, themes and concepts identified in the notes and from issues covered by the interview schedule. The index was then applied to four of the eleven interview transcripts and it was further refined.

6.4.4c Indexing

The thematic framework or index was then applied to all the transcripts. Each theme was numbered and these numbers were used in the margins of the interview transcripts to index where the themes occurred in each transcript. Some descriptive notes were also placed in the margin to clarify how the text related to the theme under which it was being indexed. When any new thematic material was identified, a new theme was added to the framework

or index. This process of indexing the data not only allowed easy identification of passages and themes in the subsequent stages of analysis, but also showed interconnections between themes when different indexing numbers occurred close together and sometimes in the same section of text. These interconnections or patterns, when they occurred in more than one transcript, helped the researcher to begin to see associations of issues and themes that were developed in the later stages of the analysis.

6.4.4d Charting

During this stage, the data were taken out of their original contexts and placed in charts. There was one chart for each one of the identified themes. Its columns were for each sub category of the theme. The sub categories were designed to show the different aspects of the various issues raised by the respondents related to each theme. The rows of the chart were for each respondent or case. Figure 6.4 is an example of one of the charts used for a theme indexed as areas of debate and conflict. Respondents' data were summarised and recorded in the appropriate section of the chart. A page reference from the interview transcript was used to enable the researcher to find the original data easily.

Figure 6.4 Example of a Chart Used During the Analysis Process

Case	8 Areas of Debate and Conflict				
	Terminology (protocol vs. guideline) 8.1	Individual practice preference vs. safe practice through standardisation and the use of evidence 8.2	Personalities' impact on the process of implementation 8.3	Oxygen face mask over end of endotracheal tube vs. use of pressure support ventilation mode 8.4	Flexibility vs. prescription 8.5
1					
2					
3					

6.4.4e Mapping and interpretation

Ritchie and Spencer (1994), suggest that the objectives of qualitative analysis are defining concepts, mapping the range and nature of phenomena, creating typologies, finding associations, providing explanations and developing strategies. The importance of each of these depends on the original purpose of the research and the research question. It is during the mapping and interpretation stage that these objectives come to the forefront of the analysis process.

The research question for this study is ‘does the implementation of a clinical guideline for early extubation of adult coronary artery bypass graft patients affect patient outcomes?’ In particular, this qualitative study seeks to explore the guideline implementation process. Firstly, to find explanations for the impact of the guideline on practice as identified by the interrupted time series data, and secondly to suggest what development and implementation strategies may have contributed to success of the process or to identify alternative strategies that could be used in future. Of the objectives of qualitative analysis identified by Ritchie and Spencer (1994), finding associations, providing explanations and developing strategies were the most important for this study.

During the mapping and interpretation stage of the analysis the researcher made more connections and associations between the content of some of the indexed themes.

Overarching themes or concepts were identified as the result of these connections and associations. The indexed and charted themes developed in the previous stages of the analysis provided the categories and subcategories of the overarching themes.

6.5 RELIABILITY AND VALIDITY

In chapter three, the debate about reliability and validity in qualitative research was touched on. It was suggested that reliability and validity are viewed differently from how they are in the positivist paradigm of quantitative research. Under the umbrella of the naturalistic paradigm, where qualitative research sits, there are further sub divisions of this philosophical stance that can influence the researcher's search for the truth, which, it may be argued is the goal of all research (Lincoln and Guba, 2000). These viewpoints inevitably have differences, which influence how various ways of ensuring high quality research are interpreted. Although not a full ethnography, this qualitative study draws from the tradition of applied practitioner ethnography. Its philosophical stance is one of subtle realism (Hammersley, 1992).

There is debate about the best way to establish the quality of ethnographic research. Denzin (1997) suggests that there are a multitude of criteria for evaluation each influenced by the researchers' philosophical standpoint. He sees the resulting tensions as a potential to sharpen and clarify differences and similarities and so help develop our understanding of how to evaluate ethnographic research. One such debate concerns the current study and it is presented below to help the reader evaluate the quality of this piece of research.

Lincoln and Guba (1985) suggest four criteria for checking the trustworthiness or reliability of qualitative research. These are credibility, dependability, confirmability and transferability. Polit et al. (2001) refer to Lincoln and Guba's (1985) criteria as credibility, dependability, neutrality and transferability. However, Hammersley (1992) suggests that the conceptualisation of Lincoln and Guba's (1985) criteria is not sound enough. He suggests that there is some lack of clarity between the criteria and the means by which the reader can assess whether the criteria have been met. Hammersley (1992) suggests that

credibility, dependability (consistency), confirmability (neutrality) and to some extent transferability are more appropriately seen as means of assessing the validity of the research than as contributing to its reliability. Validity is conceptualised as truth, or the extent to which the phenomena described, explained or theorised about is represented accurately.

Hammersley (1992) suggests that the validity of the research should be assessed firstly to see whether it seems plausible and then if it is not plausible to see whether it is credible. Plausibility is the extent to which the description, explanation or theory seems plausible in light of the reader's existing knowledge. Credibility is assessed by reviewing the evidence provided to support the description, explanation or theory. The evidence itself should be firstly assessed for plausibility, and then if it does not seem plausible it should be assessed for credibility and so on.

In this study, the themes that emerged from the data analysis (results) are presented in chapter nine and are supported by discussion of the data in chapter twelve. Quotations from participants are given as evidence to support and illustrate the themes. The reader can decide on the validity of the researcher's interpretation of the results by assessing the themes for plausibility and credibility.

Hammersley (1992) suggests a second criterion for assessing the quality of ethnographic research. This is relevance. The means of assessing the relevance depend on its intended audience, e.g. fellow researchers or practitioners. The relevance can be assessed by means of the importance of the topic, and/or the contribution of the findings to the literature and/or practice.

This research is intended for an audience of both researchers and practitioners and so the importance of the topic and the contribution of the findings to research and practice are important. The importance of the topic is addressed in chapter one. The need to extend the knowledge base of both the practice of early extubation of adult cardiac surgical patients and how to implement clinical guidelines effectively in practice is developed in the literature review (chapter two). Chapter twelve contains a discussion of the findings of the qualitative study in relation to the literature on the development and implementation of clinical guidelines. The conclusion (chapter thirteen) includes sections on the implications of this study for both practice and research. These sections of the thesis should facilitate the reader's assessment of their own and the researcher's judgement on the relevance of the study to practice and research.

Hammersley's (1992) critique of Lincoln and Guba's (1985) criteria for judging the quality of ethnographic research is discussed below. Each of the four criteria (credibility, dependability, confirmability and transferability) is related to this qualitative study. A discussion of the criteria follows, using Hammersley's (1992) critique, to demonstrate how the aspects of the study conduct can be used as a means of assessing plausibility/credibility or relevance.

6.5.1 Credibility

Credibility of data is the extent to which the reader has confidence in the truth of the data (Polit et al., 2001). Credibility relates to both the conduct of the research and how this is demonstrated. Similarly, Hammersley's (1992) critique would indicate that the demonstration of credible conduct of research contributes to its validity.

Lincoln and Guba (1985) suggest that prolonged engagement with those under investigation is one important way of establishing credibility. As an insider (i.e. a staff nurse) at the research site, the researcher was already immersed in the culture, which should give the credibility of having an in-depth understanding of the culture. Some of the participants actually observed that being a clinician gave the researcher credibility as a researcher (see chapter nine, section 9.5).

Developing trust with the participants is an intended outcome of prolonged engagement. In this study, being an insider may have meant the researcher was already viewed as a trusted colleague and clinician. This could mean that distortions in the data caused by participants' reactions to an outsider may have been avoided (Lincoln and Guba, 1985). However, from the researcher's reflections she did consider that, although being an insider may have given credibility to the researcher, her role as a staff nurse may have meant respondents may not have wished to give certain information to a fellow member of staff in that particular role. Although this sort of bias or distortion in the data remains a possibility, the variety of different views expressed by participants seems to balance this risk. Hammersley's (1992) discussion includes the advantages and disadvantages of practitioner ethnography and the value of using triangulation of data sources to help establish reflexivity in the research (see section 6.3 above).

Hammersley (1992) argues that practitioner ethnography is a credible means of gaining the participants' trust in order to gain access to good quality data. In this study, the evidence provided through triangulation of data should enhance the credibility and consequently the plausibility of the research. This means the reader can assess the validity of the research as presented by the researcher.

The need to maintain a critical view of the culture as a researcher (Brewer 2000) was perhaps a more challenging aspect of the research for an insider than developing trust with participants and gaining access. Maintaining a balanced stance on the issues associated with the development and implementation of the guideline and a conscious effort to understand the different views of participants was the approach adopted by the researcher, to ensure the data collected represented participants' different perspectives and experiences. Reflections in the researcher's diary illustrated this position.

Although my view is that both ways of extubating patients seem safe, I think because of my ICU background people assume I think ASB [pressure support mode of ventilation] is best. Today I made the effort to suggest the advantages of using the face mask option, when a group of staff were discussing the different approaches to extubation in the staff room. I wondered if I was over compensating for being seen as an ASB supporter, however I was trying to put another perspective into the conversation which was going along the lines of ASB is best. Was I acting as a nurse who wanted to get my colleagues to think about alternative perspectives, or a researcher trying to protect my image of seeing good things about both practices? Are these mutually exclusive motives?

Using Hammersley's (1992) criteria of plausibility, the researcher's point here could be judged as valid or invalid, by assessing the credibility of the evidence from the reflective diary used to support it. That is, to what extent does the quotation support the view that the researcher was concerned with maintaining a balanced stance on the issues associated with the development and implementation of the guideline and making a conscious effort to understand the different views of participants was the approach adopted by the researcher.

Polit et al. (2001) suggest that research can use triangulation to enhance credibility because it increases the chances of errors being identified. However, if all data is considered to be a construction by participants and the researcher (see section 6.3), there are unlikely to be errors contained within it, just different perspectives of the phenomenon being studied. This does not mean that various forms of triangulation are not important means to establishing the plausibility and, consequently the validity of the research findings.

Interviewing a diversity of participants, about the development and implementation of the clinical guideline contributed data source triangulation (i.e. using many sources of data) (Polit et al., 2001). This type of triangulation clearly is likely to increase the variety of perspectives of the 'truth'. Data saturation in the participant interviews is a way of achieving data source triangulation. Therefore, attempting to reach data saturation (section 6.4.2b) in this study contributes to its validity.

Method triangulation (using more than one type of data collection method) is another means of triangulation (Polit et al., 2001). Although the primary method of data collection in this study was interviews with participants, the data from the reflective diary was a second method of data collection. However, the diary's primary role was to enable reflexivity about the researcher's impact on the research to complement the interviews, rather than a record of observation in the field, as might be the case in a full ethnography. As this qualitative study was not conceived as a complete ethnography, but rather as a study using an applied ethnographic stance to inform data collection and analysis of interviews, establishing triangulation of methods was limited. Within these limitations, using the two methods of data collection should contribute to the validity of the research.

Theory triangulation is another way of enhancing credibility (Polit et al., 2001). This is where the data are viewed from different theoretical perspectives, e.g. using the cultural perspective in ethnography to interpret the data and then comparing it with an interpretation using another theoretical perspective such as feminist theory. If certain facts are consistent with more than one theory, they may be more credible. However, Lincoln and Guba (1985) argue that facts are not necessarily more believable because they have meaning within more than one theory and they consider prolonged engagement and persistent observation to be more valuable in establishing credibility. Theory triangulation was not used in the current qualitative study.

Lincoln and Guba (1985) suggest that one way to strengthen the credibility of a study is to use more than one person to collect and analyse the data (investigator triangulation). However, if each researcher was participating in the setting and was co-creating the data contained in the interview with the participant (Hammersley, 1992), then although the number of researcher's could be argued to give more perspectives of the truth, no one researcher's perspective would be nearer the truth than any other's perspective.

There would be advantages and disadvantages to having more than one researcher collecting and analysing data as there was in the current study. More than one researcher might give different opportunities to assess the impact of the researcher on the setting and what the respondent's reactions to different researchers revealed about the setting. That is, respondents might react differently to different researchers and so their data constructions may give different perspectives. However, it could be argued that one researcher could have less of an impact on the setting and so cause less disruption to the independent truth sought through constructing data in interviews. In this study, more than one researcher would not necessarily have improved the credibility of the data.

Having more than one researcher involved in the analysis could be considered a way to facilitate reflexivity, through discussion of the researchers' cultural assumptions. This could potentially increase the insights into the objective truth contained in the data. Having a researcher who was not a practitioner researcher would have been particularly useful for this type of reflexivity in this study. The development of categories and themes by more than one researcher could also help identify plausible (using Hammersley's (1992) criteria) themes. If a particular category or theme were obvious to more than one researcher, it would also be likely to be plausible to the research's audience. In spite of only having one researcher in this study, discussions with a supervisor were used to explore and test the plausibility/credibility of the data collection progress and the emerging themes from the analysis. External checks, such as this, can contribute to credibility (Polit et al., 2001).

Lincoln and Guba (1985) suggest that member checks (i.e. asking participants to check their data and how it has been interpreted) also contribute to credibility. If the researcher had done this, the credibility of the current study may have been even stronger, by allowing the participants to identify whether the researcher had interpreted their data credibly. However, Hammersley (1992) argues that the participants do not need to judge the credibility of the researcher's interpretation of their data. All interactions in the research can be considered to be socially constructed by the participant and the researcher. He argues that participants' accounts are no more likely than the researcher's account to convey the 'truth'. This is because all accounts are only individuals' representations of events, situations, or behaviours. Participants do not have any more 'privileged' access to the truth than do researchers (see discussion of naïve realism and subtle realism in section 6.3).

Hammersley (1992) also raises the issue that participants may not agree with the researcher's representations for a variety of reasons. He also contends that Lincoln and Guba's (1985) view of member validation confuses the difference between criteria to validate the research and data collection strategies. Taking Hammersley's (1992) critique in to consideration, then, it was not necessary to the validity of the research for the interviews to be checked by the participants.

Good practice in ethnographic interviewing can include continuing interviewing until no new data emerges (data saturation). However, in this study there was a tension between this best practice and the practicalities of keeping a mixed methods case study manageable. Although all those who participated in the development and implementation of the guideline were interviewed, it was not feasible to interview all the clinicians who used the guideline because there were approximately 50 members of staff. It is possible that data saturation was not reached with the smaller sample used.

In spite of this potential limitation, the participants expressed a variety of views, including conflicting ones. Polit et al (2001) suggest that searching for disconfirming evidence contributes to credibility. When one particular participant expressed some views that were quite different to the others, another participant was selected to see whether a further range of emerging views needed to be explored. The additional interview did not raise any further conflicting views and no further interviews were conducted. The variety of views collected in the data strengthens the potential that data saturation was reached. Incorporating the whole variety of views into the data analysis should also strengthen its plausibility and therefore the validity of the qualitative study findings.

6.5.2 Consistency or Dependability

Polit et al. (2001) liken the concept of dependability in qualitative research to that of reliability in quantitative research. Dependability therefore relates to the consistency of the data and its collection and interpretation and takes into consideration whether these are influenced by various conditions that may change over time. Lincoln and Guba's (1985) term this criteria 'consistency'. However, Hammersley (1992) suggests that Lincoln and Guba's (1985) criteria of consistency of data is more a means of judging its validity rather than establishing its reliability (see section 6.5). Therefore, being consistent in data collection and interpretation increases the chances that the study findings are valid.

The data were collected in a systematic manner, by one researcher, using semi-structured interviews guided by an interview schedule (See Appendix B). All interviews were taped, with the participants' consent, and fully transcribed. These and the thematic index and analysis charts were discussed with two research supervisors in order to highlight any inconsistencies (see sections 6.4.2 and 6.4.3) for further details of data collection and analysis methods). This process could have been strengthened further by sending data and associated documents to an expert who was not associated with the researcher's supervision process. This would have reduced the risk of any conflict of interests the supervisors may have had. Following Hammersley's (1992) critique, this process for establishing dependability or consistency of data collection and analysis. By following the above suggestions, particularly the analysis process and recommendation to send provisional analyses to an external person, could help improve the validity of the findings by increasing the chances that it would be judged plausible and credible by its intended audiences.

Keeping clear records of the processes of data collection and interpretation is known as an audit trail or an inquiry audit (Lincoln and Guba, 1985 and Polit et al., 2001). In this study, the audit trail is limited to the schedule for the interviews and the researcher's reflections because it was not a complete ethnography, needing a clear trail of the process of data collection, indexing, further data collection and analysis. This view of audit trails coincides with the idea that reliability is improved, by demonstrating that the researcher is measuring what they mean to measure and that someone else would get the same results using the same measurement tools and following the same audit trail for data collection and analysis.

There are, however, some arguments that ethnography can never be exactly replicated because of the changing nature of the settings where research has taken place. Therefore, it follows that if another ethnographer did a similar study, following the same processes, the findings would be different because the setting is constantly changing and being reconstructed by the participants. Perhaps, then, Hammersley's (1992) criteria of relevance is of more use in establishing the quality of ethnography, than attempting to demonstrate its reliability.

Considering Hammersley's (1992) criteria of relevance, this study is aimed at both researchers and practitioners. The importance of the topic, if taken as the impact of clinical guidelines in nursing and healthcare more generally, can be judged by both researchers and practitioners. As will become apparent in the literature used for the discussion in chapter 12, there is considerable interest in understanding how research evidence is used in practice by clinicians, and how this understanding can be used to improve practice outcomes. The United Kingdom government research programmes also include funding for this area. There has also been government investment in guideline development to help improve practice (National Institute for Clinical Excellence (NICE) in England and Wales and the

Scottish Intercollegiate Guideline Network (SIGN) in Scotland. Clinicians are also interested in the role of guidelines and their impact on practice. There is debate about their usefulness and their role in local and national policy. In nursing, guidelines are also used to facilitate extended practice roles (see chapter twelve for more discussion of these issues).

The findings are discussed in relationship to existing knowledge in chapter twelve, which can help the reader judge the contribution they make to knowledge. Because the discussion focuses on the research literature, the relevance to researchers should be clear. This choice of presentation in the discussion means that relevance for practitioners is not addressed so explicitly. However, the results presented in chapter nine should be useful to practitioners when assessing their relevance to their own practice settings. The conclusion, (chapter thirteen), contains the implications of this research for both research and for practice.

6.5.3 Confirmability

Confirmability relates to whether more than one person is likely to agree about the meaning of the data and their relevance (Lincoln and Guba, 1985 and Polit et al., 2001).

Confirmability could therefore be seen as a means to assess the plausibility of the findings, using Hammersley's (1992) criteria. Audit trails are useful to help establish confirmability as well as dependability (Polit et al, 2001). One supervisor was asked to analyse independently a sample of interview transcripts. The supervisor was then asked to compare their analysis with the thematic index developed by the researcher and was able to confirm the researcher's interpretation. It could be argued that this confirmation adds to the research's credibility and subsequent validity (Hammersley, 1992).

6.5.4 Transferability

Transferability is a similar concept to generalizability in quantitative research. It is therefore about how well the findings can be transferred to other settings (Polit et al., 2001). Including enough description so that the reader can assess the applicability of the findings to other settings strengthens transferability. This presented a challenge in the current study because it was a single site and too much description, particularly of the participants' roles and responsibilities generally and within the extubation guideline project, could have compromised the confidentiality of the participants' data.

The actual site was a tertiary referral centre cardiac intensive care unit for adult cardiac surgical patients. It was in the United Kingdom and part of a National Health Service Trust.

Procedures performed on elective, urgent or emergency patients were as follows:

- coronary artery bypass grafting (CABG)
- heart valve operations
- combinations of CABG and valve replacements
- aortic surgery (typically aortic root replacements and aortic aneurysm repairs)
- atrial septal defect and ventricular septal defect repairs (ASD and VSD respectively, which are abnormal holes between chambers of the heart)
- myomectomies (removal of a section of myocardium or heart muscle).

The site had eight to nine intensive care beds and six to seven high dependency beds.

Nurse to patient ratios were typically one to one for the intensive care beds and one to two or three for the high dependency beds. Beds were used flexibly depending on the needs of the patients.

Helping readers assess whether this research could apply in their practice settings, is clearly important. However, although Polit et al., (2001) liken transferability to generalisability in quantitative research, Hammersley (1992) discusses the issue of generalisability in ethnographic research with more subtlety and in greater depth. Hammersley (1992) suggests that if an ethnographic study seeks to build theory, this theory can then be tested and developed in other ethnographies in other settings. The argument is that, because theory is abstracted from the data in one setting, it is not necessarily dependent on that setting and the time it was collected. However, further ethnographies to explore the theory are essential, before the generalisability of the theory can be established.

Since this qualitative study aimed to explain rather than theorise, the findings cannot be generalised in the sense discussed by Hammersley (1992). Further ethnographic research could, however, be designed to build theory in the field of guideline development and implementation. This does not mean that readers cannot use their judgement to assess whether the findings of this study might be transferable and useful to their own practice settings or might inform their research.

CHAPTER SEVEN

SYSTEMATIC REVIEW RESULTS

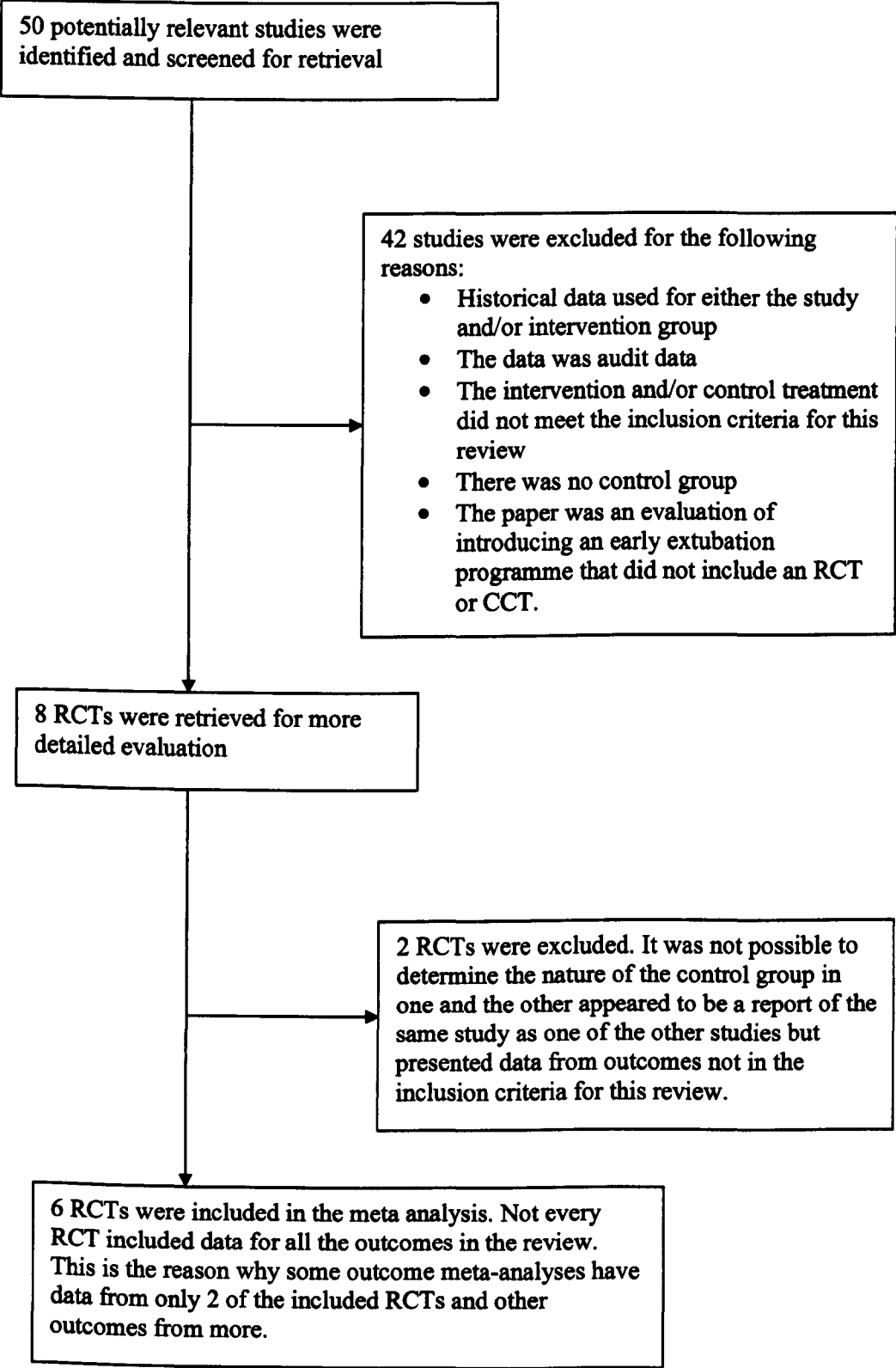
The results of the systematic review are presented below. The results of the search strategy are presented below (section 7.1) (see chapter four for details of the methodology and Appendix C for the search strategy) and the tables associated with these results are in Appendix E. The results of the meta-analysis for each of the outcomes identified in the methodology (chapter four) are presented in table and graph form and then discussed. Qualitative analyses of the outcomes that were not included in the meta-analysis are also presented. The primary outcomes are presented first (section 7.2) followed by the secondary outcomes (section 7.3).

7.1 RESULTS OF THE SEARCH

7.1.1 Description of Studies

The literature search results and subsequent selection process for studies included in the review are summarised in a flow diagram (Figure 7.1), as suggested by Moher et al. (1999). Searching yielded eight potential studies for the review (see Appendix E, Table 1 – Characteristics of Included Studies and Table 2 – Characteristics of Excluded Studies). Six studies were finally included in the review with a total of 871 patients allocated to either intervention or control group. Of these, approximately half (404) were from one study (Reyes et al., 1997). All the participants were adults and three studies (Cheng et al., 1996a, Berry et al., 1998 and Michalopoulos et al., 1998) excluded patients over 75, 70 and 71 years of age respectively. The majority of patients had coronary artery bypass graft (CABG) surgery (707). One hundred and thirty three patients had cardiac valve surgery, 20 patients had both CABG and valve surgery and 11 had another type of cardiac surgery. All

Figure 7.1 Flow Diagram of the Stages in Study Selection and Use in the Meta-Analysis (based on Moher et al., 1999)



the patients who had valve or CABG and valve surgery or other sorts of cardiac surgery come from one study (Reyes et al., 1997). The majority of patients had elective surgery (846). Only Reyes' study included urgent and emergency cases (20 and four patients respectively). All the studies excluded patients deemed to be at high risk, although criteria varied between studies. The included studies provide evidence limited to only part of the cardiac surgical population of the mid to late 1990s. (See Appendix E Table 1 - Characteristics of included studies and Additional Tables 1, 2 and 3 for further details).

Two studies were excluded. One (Koslov et al., 1995) was ineligible for analysis because the methodology used was not clearly stated, so it was not possible to tell whether it was a prospective clinical trial nor whether the patients were randomised to study and control groups. Another (Cheng et al., 1996b) was excluded, as it appears to be a report of the same study as Cheng et al. (1996a), but focusing on outcomes that are not the subject of this review.

7.1.2 Methodological Quality

Sources of potential bias in the included studies were identified (see Appendix E, Table 1 - Characteristics of Included Studies). These sources of bias were selection bias and performance bias. The results from all the studies, except Cheng et al. (1996a), may have been affected by selection bias due to the absence of adequate allocation concealment.

The results from all the studies may have been affected by performance bias due to the inability to blind those providing and receiving care to the intervention. The results from all the studies, except Quasha et al. (1980) and Reyes et al. (1997), may have been affected by performance bias driven by the studies' protocols, because the care that the intervention group and control group received differed by more than time to extubation. Specifically, the early extubation groups received a different anaesthetic (e.g. less fentanyl) than the

control groups (more fentanyl). Any difference in outcome may therefore be confounded by this factor. (See Appendix E, Table 1 - Characteristics of Included Studies and Additional Tables 1, 2 and 3).

Assessors for some of the outcomes were blinded. Myocardial infarction or ischaemia was diagnosed by assessors blinded to the study groups in three studies (Quasha et al., 1980, Reyes et al., 1997 and Berry et al., 1998). Atelectasis was diagnosed on chest X-rays by assessors blinded to the study group in two studies (Cheng et al., 1996a and Reyes et al., 1997).

7.2 PRIMARY OUTCOMES

The results for each of the outcomes are presented in a table and in a graph. The table shows a comparison of the relative risk or the weighted mean difference of the outcome for early extubation versus conventional extubation. The graph shows the results for each study included in the analysis and the results of the combined data (the diamond shape at the bottom of the graph). If the diamond straddles the vertical line the results are not significant and the null hypothesis cannot be disproved.

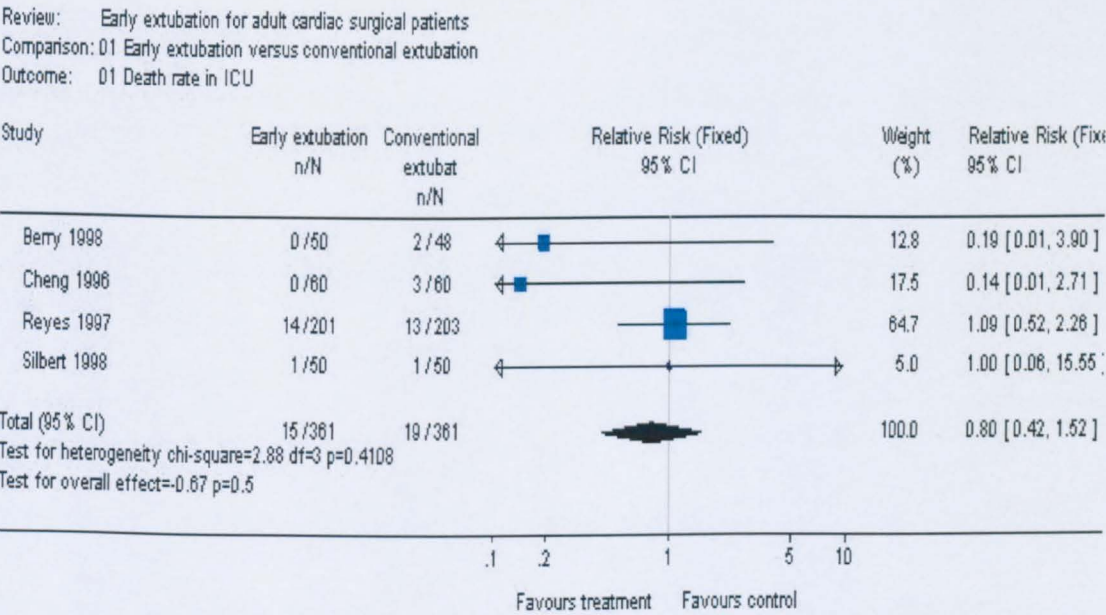
7.2.1 Mortality

7.2.1a Intensive care unit (ICU) mortality

Table 7.2.1a Early Extubation versus Conventional Extubation: ICU Mortality				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Death rate in ICU	4	722	Relative Risk (Fixed) 95% CI	0.80 [0.42, 1.52]

There was no evidence of a difference in the risk of mortality between the early and conventional extubation groups. The relative risk was 0.80 (95% confidence interval 0.42 to 1.52 ($p = 0.5$)). Four studies were included in the analysis for ICU mortality risk, Cheng et al., 1996a, Reyes et al., 1997, Berry et al., 1998 and Silbert et al., 1998.

Figure 7.2.1a Graph of ICU Mortality

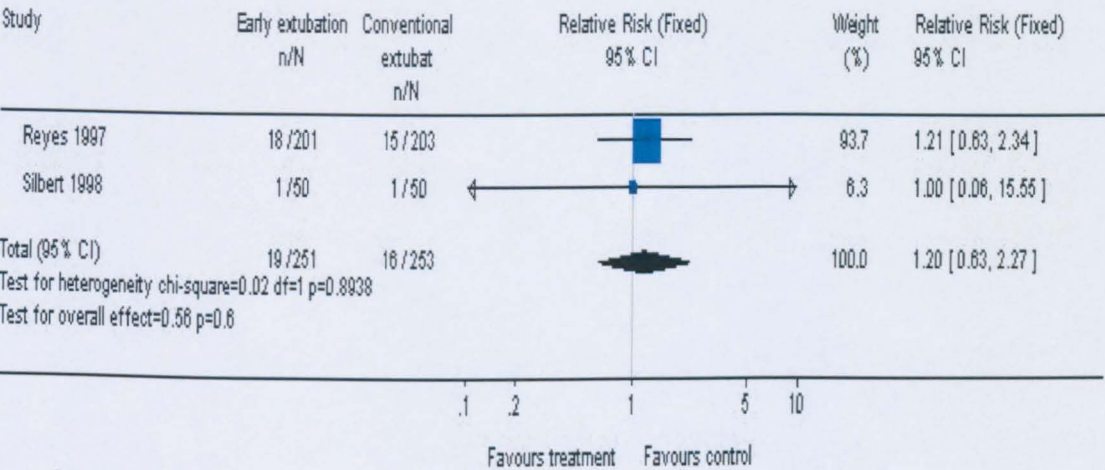


7.2.1b Thirty Day Mortality

Table 7.2.1b Early Extubation versus Conventional Extubation: 30 day mortality				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Death rate at thirty days post surgery	2	504	Relative Risk (Fixed) 95% CI	1.20 [0.63, 2.27]

Figure 7.2.1b Graph of Thirty Day Mortality

Review: Early extubation for adult cardiac surgical patients
Comparison: 02 Early extubation versus conventional extubation
Outcome: 01 Death rate at thirty days post surgery



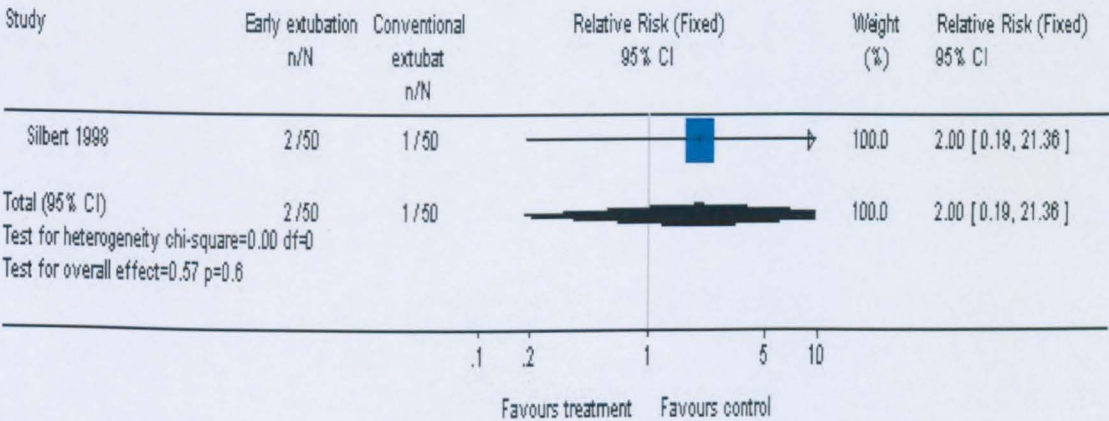
There was no evidence of a difference between the risk of thirty day mortality for the early and conventional extubation groups. The relative risk was 1.2 (95% confidence interval 0.63 to 2.27 ($p = 0.58$)). Two studies were included in the analysis for the risk of mortality within thirty days of surgery: Reyes et al. (1997) and Silbert et al. (1998).

7.2.1c Mortality between 31 days and one year

Table 7.2.1c Early Extubation versus Conventional Extubation: 30 days to 1 year				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Thirty one day to one year death rate	1	100	Relative Risk (Fixed) 95% CI	2.00 [0.19, 21.36]

Figure 7.2.1c Graph of Mortality between 31 days and one year

Review: Early extubation for adult cardiac surgical patients
Comparison: 03 Early extubation versus conventional extubation
Outcome: 01 Thirty one day to one year death rate



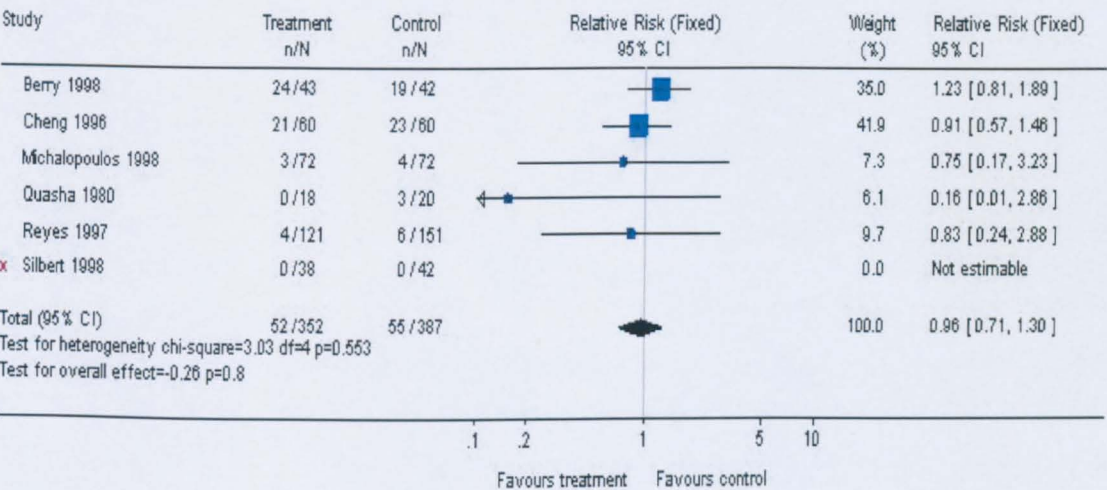
There is not enough evidence, from the Included Studies, to assess whether there is a difference in 31 day to one year mortality rates between the early and conventional extubation groups. Only one study provided data on 31 day to one year mortality rates (Silbert et al. (1998). (See Appendix E, Table 1- Characteristics of Included Studies for more details of each study).

7.2.2 Incidence of postoperative myocardial ischaemia

Table 7.2.2 Early Extubation versus Conventional Extubation: Incidence of Myocardial Ischaemia				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Incidence of myocardial ischaemia	6	739	Relative Risk (Fixed) 95% CI	0.96 [0.71, 1.30]

Figure 7.2.2 Graph of the Incidence of Myocardial Ischaemia

Review: Early extubation for adult cardiac surgical patients
Comparison: 04 Early extubation versus conventional extubation
Outcome: 01 Incidence of myocardial ischaemia



There was no evidence of a difference in the relative risk of experiencing postoperative myocardial ischaemia between the early and conventional extubation groups. The relative risk was 0.96 (95% confidence interval 0.71 to 1.30 ($p = 0.79$)). Six studies were included in this analysis: Quasha et al. (1980), Cheng et al. (1996a), Reyes et al. (1997), Berry et al. (1998), Michalopoulos et al. (1998) and Silbert et al. (1998).

Although all six studies are included in this analysis, this is a crude measurement. The number of patients suffering myocardial infarction (MI, heart attack) has been combined with the number of patients with significant ischaemia. Some other measurements, such as CK-MB (cardiac enzyme detectable in the blood and used to detect myocardial damage) levels were reported in these studies, but these measures have not been combined.

7.2.3 Postoperative Lung Function

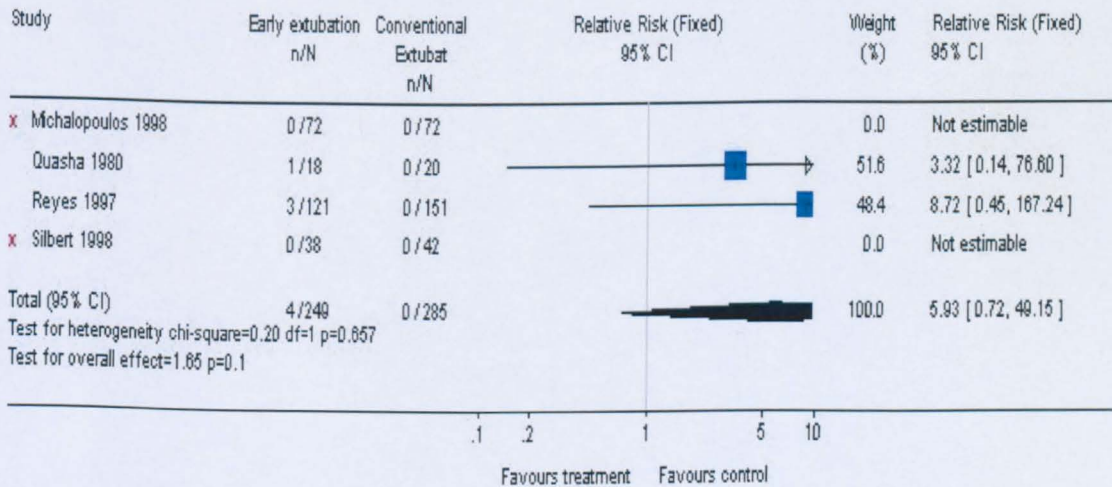
7.2.3a Reintubation within 24 hours of surgery

Table 7.2.3a Early Extubation versus Conventional Extubation: Reintubation within 24 Hours of Surgery

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Reintubation rate within 24hours of surgery	4	534	Relative Risk (Fixed) 95% CI	5.93 [0.72, 49.15]

Figure 7.2.3a Graph of Reintubation Rate within 24 Hours of Surgery

Review: Early extubation for adult cardiac surgical patients
Comparison: 05 Early extubation versus conventional extubation
Outcome: 01 Reintubation rate within 24hours of surgery



There was no evidence of a difference in the relative risk of reintubation within 24 hours of surgery for the early and conventional extubation groups. The relative risk was 5.93 (95% confidence interval 0.72 to 49.14 ($p = 0.1$)). Four studies were included in this analysis, Quasha et al. (1980), Reyes et al (1997), Michalopoulos et al. (1998) and Silbert et al. (1998). The overall incidence of reintubation is low, 4 out of 249 patients in total (1.6%).

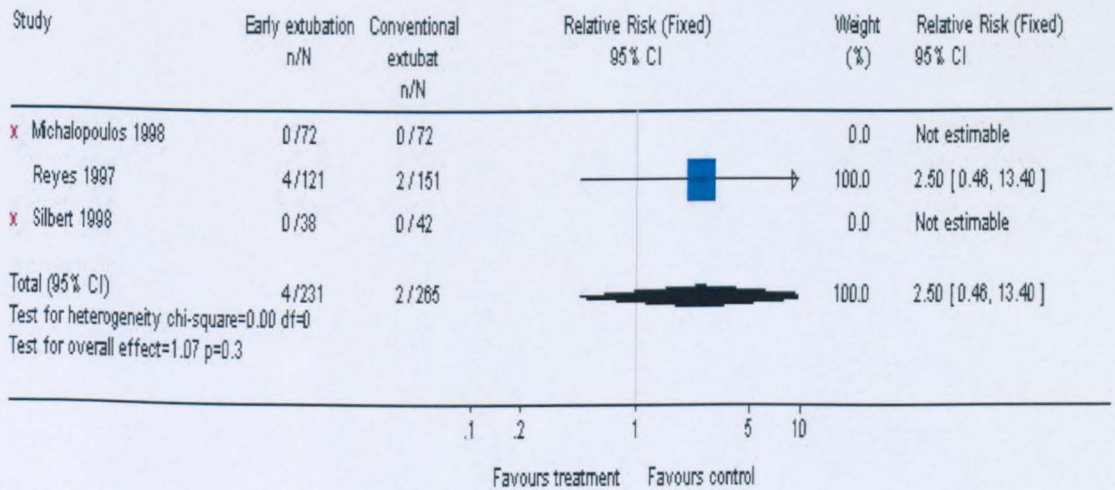
Two studies, Michalopoulos et al. (1998) and Silbert et al. (1998), had no patients reintubated in either group.

7.2.3b Reintubation later than 24 hours after surgery

Table 7.2.3b Early Extubation versus Conventional Extubation: Reintubation Later than 24 Hours after Surgery				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 reintubation later than 24hours after surgery	3	496	Relative Risk (Fixed) 95% CI	2.50 [0.46, 13.40]

Figure 7.1.3b Graph of Reintubation Later than 24 hours After Surgery

Review: Early extubation for adult cardiac surgical patients
Comparison: 06 Early extubation versus conventional extubation
Outcome: 01 reintubation later than 24hours after surgery



There is no evidence of a difference in the relative risk of reintubation after 24 hours between the early and conventional extubation groups. The relative risk was 2.5 (95% confidence interval 0.46 to 13.4 (p = 0.29)). Three studies were included in this analysis, Reyes et al. (1997), Michalopoulos et al. (1998) and Silbert et al. (1998). Two studies had

no patients in either group reintubated (Michalopoulos et al., 1998 and Silbert et al., 1998). Reyes et al's study (1997) had an overall incidence of six out of 403 patients (1.49%).

7.2.3c Respiratory dysfunction

This was measured differently in different studies and at different time points, so the results have not been combined in a meta-analysis. The findings are presented qualitatively.

Three studies measured the incidence of atelectasis at different times (Quasha et al., 1980, Cheng et al. 1996a and Reyes et al., 1997) and found no evidence of a difference between the early and conventional extubation groups. Cheng et al. (1996a), Reyes et al. (1997), Michalopoulos et al. (1998) and Silbert et al. (1998) reported on arterial blood gas levels measured by the partial pressure of oxygen and carbon dioxide in the arterial blood (PaO_2 and PaCO_2 respectively. See Table 7.1.3c and Table 7.1.3e) . The findings, when considered together, are inconclusive. Only one study measured intrapulmonary shunt (Cheng et al., 1996a) (see Table 7.1.3d). The findings showed that the intrapulmonary shunt was significantly less at four hours post extubation for patients extubated early compared with those extubated conventionally. That is, the early extubation group had fewer areas of collapsed lung that were not oxygenating blood at four hours after extubation compared with patients extubated conventionally.

7.2.3c Arterial Blood Gas Levels (Cheng et al., 1996a)

Outcome Measure	Early Extubation	Conventional Extubation	Significance
PaO2 within 30 minutes of extubation	142.5 mmHg (± 43.8)	125 mmHg (± 37.4)	p < 0.035
PaCO2 within 30 minutes of extubation	40.8 mmHg (± 4.8)	39.3 mm Hg (± 3.4)	NS
PaO2 at c. 4 hours after extubation	145.2 mmHg (± 48.8)	129.9 mm Hg (± 51.8)	NS
PaCO2 at c. 4 hours after extubation	39.6 mmHg (± 4.3)	39.6 mmHg (± 3.6)	NS

Table 7.2.3d Intrapulmonary Shunt (Cheng et al., 1996a)

Outcome Measure	Early Extubation	Conventional Extubation	Significance
Qs/Qt (intrapulmonary shunt) within 30 minutes of extubation	16.4 (± 13.6)	21.5 (± 21.5)	NS
Qs/Qt at c. 4 hours post extubation	13.3 (± 9.2)	25.1 (± 24.1)	p< 0.002

Table 7.2.3e Arterial Blood Gas Levels (Reyes et al., 1997)

Outcome Measure	Early Extubation	Conventional Extubation	Significance
PaO2 at 60 minutes post extubation	108 (± 24.5) mm Hg	100 (± 23.7) mm Hg	p = 0.006
PaCO2 at 60 minutes post extubation	39.2 (± 5.4) mm Hg	37.8 (± 5.7) mm Hg	p = 0.047

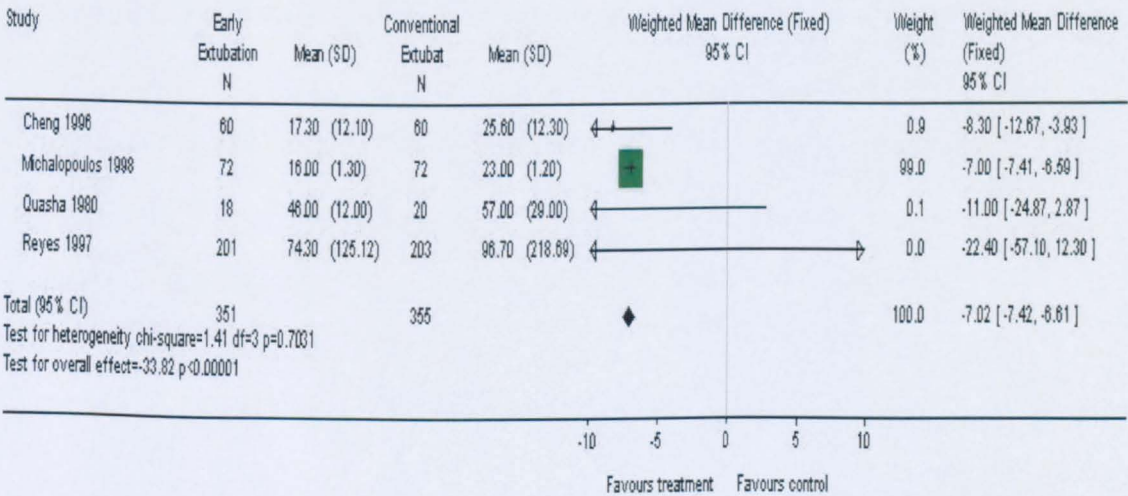
7.3 SECONDARY OUTCOMES

7.3.1 Intensive Care Unit (ICU) Length of Stay

Table 7.3.1 Early Extubation versus Conventional Extubation: ICU Length of Stay				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Length of Intensive Care Unit Stay (hours)	4	706	Weighted Mean Difference (Fixed) 95% CI	-7.02 [-7.42, -6.61]

Figure 7.3.1 Graph of ICU Length of Stay

Review: Early extubation for adult cardiac surgical patients
Comparison: 08 Early extubation versus conventional extubation
Outcome: 01 Length of Intensive Care Unit Stay (hours)



The weighted mean difference in duration of intensive care unit stay (in hours) showed a significant difference in favour of early extubation. The weighted mean difference was -7.02 (95% confidence interval -7.42 to -6.61 ($p < 0.00001$)), i.e. patients extubated early were likely to leave intensive care approximately seven hours earlier than conventionally

extubated patients. Four studies were included in the analysis, Quasha et al. (1980), Cheng et al. (1996a), Reyes et al. (1997) and Michalopoulos et al. (1998).

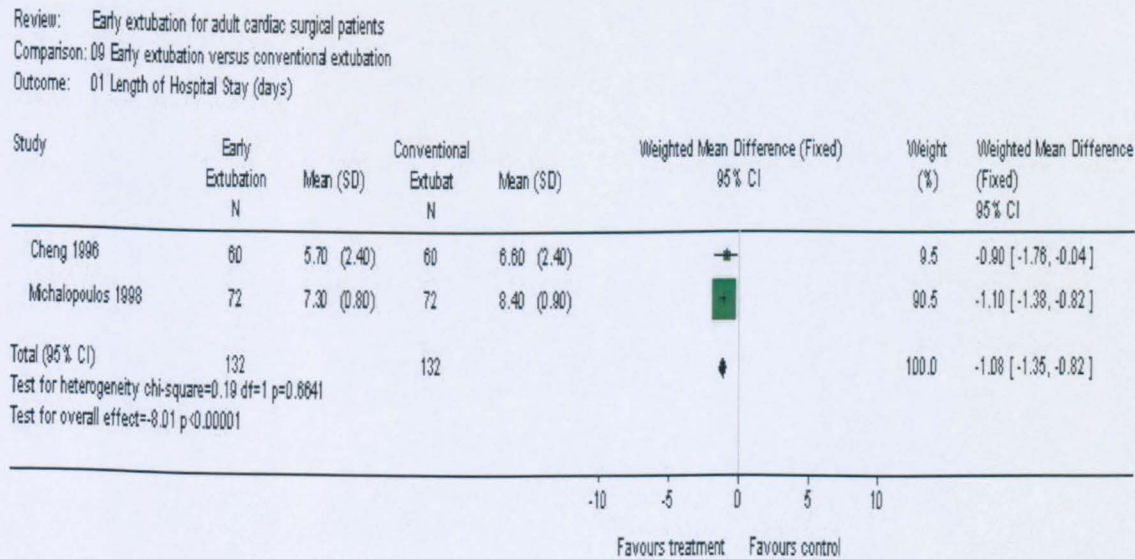
The results support the hypothesis that duration of stay in the postoperative intensive care unit is less for adult cardiac surgical patients extubated early.

7.3.2 Hospital length of stay

Table 7.3.2 Early Extubation versus Conventional Extubation Length of Hospital Stay

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Length of Hospital Stay (days)	2	264	Weighted Mean Difference (Fixed) 95% CI	-1.08 [-1.35, -0.82]

Figure 7.3.2 Graph of Hospital Length of Stay



The weighted mean difference in duration of hospital stay (in days) was significantly different -1.08 (95% confidence interval -1.35 to -0.82 ($p < 0.00001$)) in favour of early extubation, i.e. patients extubated early were likely to be discharged, on average, approximately one day earlier than those extubated conventionally. Only two studies were included in the analysis: Cheng et al. (1996a) and Michalopoulos et al. (1998).

The results support the hypothesis that the duration of postoperative stay in hospital is less for adult cardiac surgical patients extubated early.

7.4 PROFESSIONAL DECIDING WHEN TO EXTUBATE PATIENTS

No information on the professional deciding when to extubate patients was given in the papers, apart from Reyes et al., 1997 who provided information in a personal communication that the decision to extubate was made by medical staff in his study. As a result of the lack of information, the analysis comparing medical staff with non-medical staff was not possible.

7.5 SUBGROUP ANALYSIS

A subgroup analysis for early extubation at less than four hours, four to eight hours and more than eight hours was also not possible because data were not available from most of the Included Studies.

7.6 SENSITIVITY ANALYSIS

A sensitivity analysis was performed first including and then excluding Reyes et al., (1997) because of the difference in definition of early extubation. Reyes et al., (1997) defined

early extubation as seven to eleven hours, whereas the other studies defined early extubation as up to six to eight hours. Patients in Reyes et al's study were not assessed for extubation until six hours after surgery. The results of the sensitivity analysis do not alter the findings reported above.

7.7 SUMMARY OF SYSTEMATIC REVIEW RESULTS

Six randomised controlled trials (RCTs) were included in the systematic review and meta-analysis. Intensive care unit and hospital length of stays were significantly shortened by early extubation. There were no statistically significant differences between the early extubation and conventional extubation groups for the variables selected to demonstrate cardiac and respiratory morbidity and mortality. Measures selected for respiratory dysfunction could not be combined in a meta-analysis and the findings were inconclusive. There were no differences in mortality rates between the two groups. These results are discussed in chapter ten.

CHAPTER EIGHT

INTERRUPTED TIME SERIES STUDY RESULTS

8.1 DESCRIPTION OF SAMPLES

A number of variables were collected to describe the whole samples for each year of the study, i.e. January 2001 to December 2001 (year one) and January 2002 to January 2003 (year two). The guideline was implemented on 21st January 2002 and so data were collected until the end of January 2003 to give a full year of data following the implementation. The descriptive variables were used to test the null hypothesis that there was no significant difference between the two samples. Similar samples minimised the threat of simple selection (see chapter five, section 5.3 for discussion of threats to the reliability and validity of the interrupted time series analysis). The results are presented for the preoperative variables in Tables 8.1.1a and 8.1.1b, for the operative variables in Tables 8.1.2a and 8.1.2b and for the postoperative variables in Table 8.1.3.

8.1.1 Preoperative Variables

There was no significant difference in the number of men and women in the samples for year one and year two (Table 8.1.1a). There was also no significant difference in the mean age of the samples (Table 8.1.1b).

In terms of pre-existing conditions that are associated with coronary heart disease, there were significantly more patients in year 2 who were hypertensive (high blood pressure), hypercholesterolaemic (raised cholesterol levels), or had peripheral vascular disease (PVD) than patients in year 1. There was a significant difference in smoking habits between the years. The number of current smokers was more in year 2 than year one and there were more ex-smokers in year 1 than in year 2. The numbers of patients who had never smoked

Table 8.1a Preoperative Dichotomous Variables

Variable	Year 1		Year 2		Chi square	P value
	Frequency	%	Frequency	%		
N	301	-	266	-	-	-
Gender:					0.011	0.916
Men	248	82.7	219	82.3		
Women	52	17.3	47	17.7		
Previous myocardial infarction	132	44	123	46.2	0.286	0.593
Hypertension	175	58.3	177	66.5	4.04	0.044*
Hypercholesterolaemia	240	80	235	88.4	7.278	0.007*
Smoker:					6.044	0.049*
Yes	33	11	47	17.7		
No never	95	31.7	87	32.7		
No, ex smoker (for at least 6 months)	172	57.3	132	49.6		
Diabetes (Type I or II)	57	19	61	22.9	1.321	0.25
Previous rheumatic fever	1	1.3	2	3	1.904	0.168
Previous Transischaemic attack	10	3.3	9	3.4	0.002	0.967
Previous cerebral vascular accident	7	2.3	10	3.8	0.984	0.321
Previous deep vein thrombosis	4	1.3	4	1.5	0.029	0.864
Peripheral vascular disease (PVD)	46	15.3	22	12	6.653	0.01*
LV function:					7.039	0.008*
Moderate (20-40% EF)	104	34.8	65	24.5		
Good (>40% EF)	195	65.2	200	75.5		
Chronic Renal failure (creatinine >150 mmols/litre)	4	1.3	3	1.2	0.038	0.845
Type of coronary disease:					10.355	0.006*
1 vessel	1	0.4	10	3.9		
2 vessel	54	22	39	15.1		
3 vessel	191	77.6	210	81.1		

Table 8.1b Preoperative Continuous Variables

Variable	Year 1			Year 2			T	P
	N	Mean	SD	N	Mean	SD	T test	P value
Age	301	64.17	8.38	266	63.52	9.53	0.86	0.391

were similar in both years. It was difficult to assess the reliability of this data, because the information may have been better recorded for the whole of year 2. This is because standardised care pathway document was brought into use approximately 6 months into year 1. This care pathway has a standardised format for clerking patients and required the variables included in this analysis to be assessed and recorded. Before the care pathway was introduced it was up to the individual doctor or nurse practitioner to decide what to include in the clerking notes. The significance of the results in Table 8.1a should therefore be treated with caution.

The clinical effect of hypertension and hypercholesterolaemia may not be significant as these conditions are usually controlled by drug therapy. The extent of a patient's PVD could increase the risk of complications, for example, risk of stroke, if there is significant carotid artery disease. The literature review (see chapter two, section 2.3) did not, however, indicate a significant link between PVD and outcomes related to early extubation.

The effect of being a current smoker on extubation was not reported as clinically significant in the literature reviewed in chapter two. Smoking can contribute to significant lung pathology, such as emphysema, and this could contribute to prolonged ventilation, if lung function was compromised. However, the evidence of the effect of lung disease on ventilation was inconclusive (see section 2.3.1 in chapter two). In this study such patients would have been excluded if they needed treatment for lung disease. Therefore, differences

in the proportion of smokers and ex-smokers probably did not significantly affect the results.

There were no differences between the two years for previous myocardial infarction (MI), diabetes, chronic renal failure, previous rheumatic fever, transischaemic attack (TIA), cerebral vascular accident (CVA), or deep vein thrombosis (DVT).

There was a significant difference between year one and year two for the proportion of patients with one vessel, two vessel and three vessel disease (the more coronary arteries or vessels affected the more severe the disease). This variable was not consistently recorded in the medical notes and there were 61 cases (10.8%) where this information was not available. The results should, therefore, be treated with caution. The clinical significance of how many vessels were diseased would most likely be to affect the time the patient was on cardiopulmonary bypass (CPB). The greater the extent of the disease, the more bypass grafts needed and the longer the surgery (although the length of surgery would also be dependent on other factors, such as the difficulty of the case and the skill of the surgeon) and therefore the length of CPB. The length of CPB was controlled for in this study by excluding cases where the length of CPB was greater than 120 minutes (see chapter two section 2.3.2 for discussion about this issue).

There was a significantly greater proportion of patients with good left ventricular (LV) function compared to moderate LV function in year 2. This should not have affected the outcomes because research seems to indicate that it is patients who have poor LV function who may have worse outcomes following coronary artery bypass graft surgery rather than those with either moderate or good LV function (see chapter two, section 2.3.1).

8.1.2 Intraoperative Variables

For the intraoperative variables (Tables 8.1.2a and 8.1.2b) there were no differences between the number of operations performed by different surgeons, nor in the number of operations on cardiopulmonary bypass (CPB) compared with the number performed off CPB. There was a significant difference in the number of cases performed by different anaesthetists (Table 8.1.2a). Two anaesthetists performed proportionately fewer cases in year two compared to year one. The majority of these cases seemed to have been taken on by registrars. There were new registrar positions created during year two, according to the qualitative data, which probably accounted for this change in caseload. The clinical significance of this could be that different anaesthetists used slightly different anaesthetic techniques. However all of the anaesthetists used low dose opiate anaesthesia, which has been shown to facilitate early extubation (see systematic review, chapter four). The consultants were the same in both years and, although there would have been some variation in anaesthetic technique, they would have been overseeing the registrars' practice. It was not possible to control anaesthetic technique in this study, however all anaesthetists used anaesthetic techniques to facilitate early extubation. So, although this study does not have the certainty of a randomised control trial using one anaesthetic technique, the significant difference noted in the distribution of cases by anaesthetists may not have had a significant affect on the outcomes in this study.

Table 8.1.2a Intraoperative Dichotomous Variables

Variable	Year 1		Year 2		Chi square	P value
	Frequency	%	Frequency	%		
Surgeon:					3.79	0.58
1	7	2.33	8	3.01		
2	93	31	31	29.7		
3	51	17	36	13.53		
4	67	22.33	67	25.19		
5	76	25.33	74	27.82		
6	8	2	2	0.75		
Anaesthetist:					42.757	0.000*
1	23	7.67	24	9.02		
2	19	6.33	21	7.89		
3	50	16.67	48	18.05		
4	64	21.33	62	23.31		
5	20	6.67	3	1.13		
6	70	23.33	38	14.29		
7	52	17.33	43	16.7		
8 (registrars)	2	0.67	27	10.15		
On or off CPBP ¹					0.928	0.335
On CPBP	229	76.33	212	79.92		
Off CPBP	71	23.67	54	22.08		

Table 8.1.2b Intraoperative Continuous Variables

Variable	Year 1			Year 2			T	P
	N	Mean	SD	N	Mean	SD	T test	P value
Time on CPBP ¹	228	44.9	24.1	207	58.6	17.8	-6.78	0.000*

1. CPBP = cardiopulmonary bypass

For patients whose operation was on cardiopulmonary bypass (CPB), patients in year two were on CPB significantly longer than patients in year one (Table 8.1.2a). Although there is some evidence that the length of CPB can affect length of postoperative ventilation, this appears to be for CPB of two hours or more (see chapter two, section 2.3.2). The samples were selected to exclude patients with two hours or longer on CPB, therefore there is

unlikely to be any clinical significance in the differences between the two samples' CPB times.

8.1.3 Postoperative Complications Variables

For the postoperative complication variables (Table 8.1.3) there were no significant differences between year one and two. This indicates that overall the implementation of the clinical guideline for extubation did not increase complications of extubation nor did it affect hospital length of stay or 30 day readmission rates. The low incidence of complications means the results should be treated with caution. Reintubation rates were not significantly different between year one and year two and were low in both years. Because of the small numbers of reintubations, there were not enough monthly cases of reintubation to conduct a reliable interrupted time series analysis for this variable.

Table 8.1.3 Postoperative Complications Variables

Variable	Year 1		Year 2		Chi square	P value
	Frequency	%	Frequency	%		
Reintubation	9	3	16	6.02	3.036	0.081
Primary reasons for reintubation:						
Cardiac	5	1.67	4	1.5		
Respiratory	3	1	11	4.14		
Combination	1	0.33	2	0.75		
CPAP ¹ post extubation	20	6.69	22	8.33	0.549	0.459
In hospital death	6	2	3	1.13	0.685	0.408
30 day readmission rate	14	4.7	11	4.14	0.105	0.746

1. CPAP = continuous positive airway pressure

8.1.4 Summary of Description of Samples

Although there were some statistically significant differences between the samples, these may not have been clinically significant. Technically the null hypothesis that there was no

difference between the samples for year one and year two is rejected, however where the samples differed their clinical impact on the outcomes may not be significant.

8.2 COMPARISON OF KEY OUTCOME MEASURES FOR THE WHOLE SAMPLE OF EACH YEAR

There were no significant differences between the samples for the postoperative (Table 8.2a) and within person control variables (Table 8.2b). These variables, with the exception of length of time needing CPAP, are further explored in the interrupted time series analysis. There are not enough monthly cases of patients needing CPAP to produce a valid interrupted time series analysis. The results for length of time needing CPAP, for the whole sample, should be treated with caution because of the small numbers involved. The incidence of complications following CABG surgery is low, including the need for CPAP.

The Mann Whitney U test for the comparison of time in days to discharge is significant, although the median for both years is the same, i.e. five days. The lower quartile and the median for both samples are the same, i.e. five days. The upper quartile is six days for year one and seven days for year two. The main difference in the samples is in the maximum values. In year one the maximum length of stay was 60 days and in year two it was 50 days. In each year this represents only one patient. In year one there were 5 other patients whose length of stay was between 20 and 40 days and in year two there were about 6 patients with a similar length of stay. When the cases are ranked for the Mann Whitney U test, the differences in the distributions of the samples mean that the median ranked case is statistically significantly different between the two years' samples. In spite of this difference, the clinical significance is probably that the majority of patients in both samples were discharged within 6 days.

Table 8.2a Comparison of Key Outcome Measures for Whole Yearly Samples

Variable	Year 1		Year 2		Mann Whitney U	Significance
	N	Median	N	Median		
Time to Extubation	301	240 (mins)	266	232 (mins)	85779	0.8797
Time to transfer to HDU ¹	298	380 (mins)	260	352.5 (mins)	84678	0.4654
Time to SV on fiO ₂ 0.40 ²	296	462.5 (mins)	262	382.5 (mins)	84922.5	0.2492
Time needing CPAP	20	12 (hours)	22	15.5 (hours)	379.5	0.2065
Time to Discharge	292	5 (days)	263	5 (days)	77285	0.0019*

1. HDU = high dependency unit

2. SV on fiO₂ 0.40 = self ventilating on a fraction of inspired oxygen of 0.40 (i.e. patient breathing for themselves on 40% oxygen)

Table 8.2b Comparison of Within Person Controls for Whole Yearly Samples

Variable	Year 1			Year 2			T	P
	N	Mean	SD	N	Mean	SD	T test	P value
Colloid Fluid Balance in mls	300	2268	748	266	2342	867	-1.08	0.282
No. of ABGs ¹	300	11.51	2.63	266	11.71	2.82	-0.87	0.384

1. ABG = arterial blood gas sample

8.3 RESULTS OF THE INTERRUPTED TIME SERIES ANALYSIS

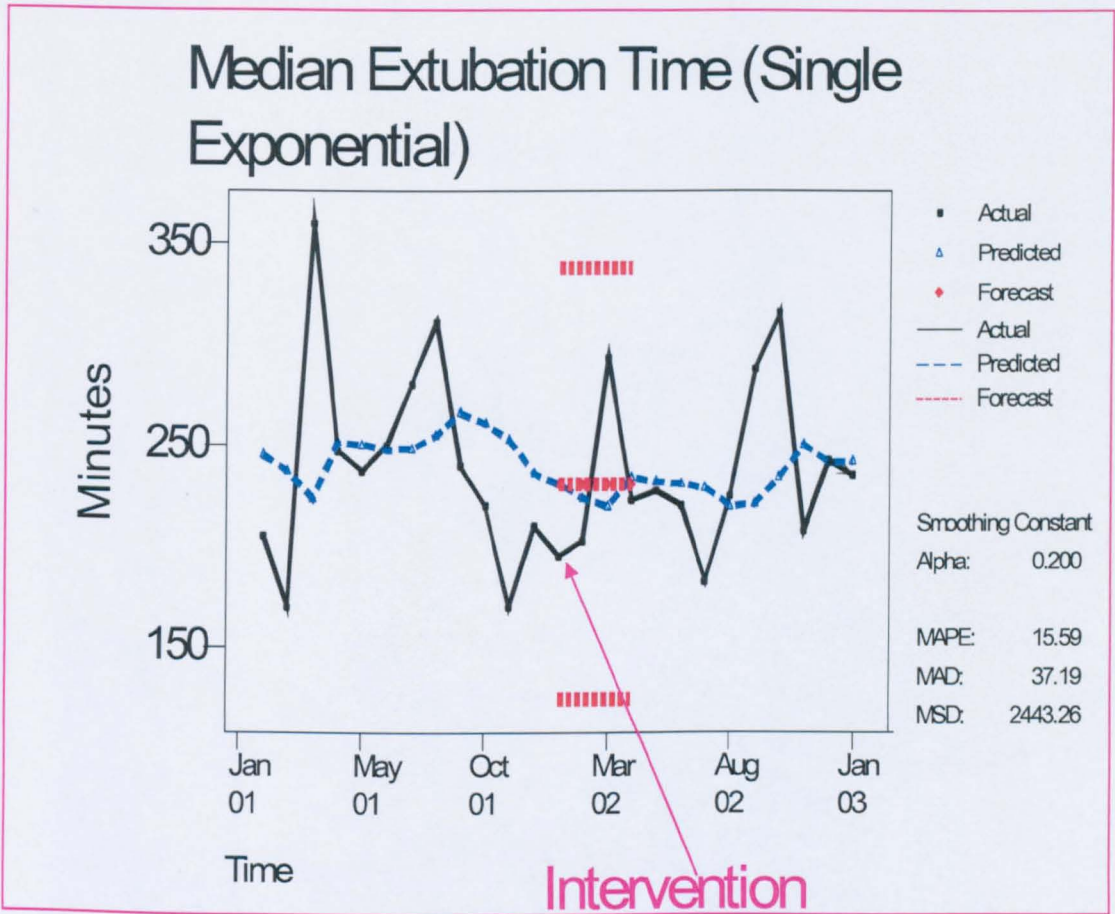
The variables time to extubation, time to self ventilating on 40% oxygen, time to transfer to HDU (or ICU length of stay), and time to discharge from hospital (or hospital length of stay) were analysed using an interrupted time series model. The variables chosen for the

within person control, colloid fluid balance and number of arterial blood gas samples were also analysed using an interrupted time series model and are presented in section 8.3. (See chapter five, section 5.5.3 for details of the data analysis methods).

The results for each variable are presented below. Each result is presented in graph form. The black line represents the actual values from the data collected. These results were smoothed using either a single exponential or double exponential model depending which model provided the best fit. The smoothed values are in blue. The first year's data were used to forecast the first three months of the second year's values, as if the guideline had not been implemented. The forecast is presented in red. The central line is the result and the two outside lines show the confidence interval. If the smoothed values of the second year (blue line) fall outside the forecast confidence intervals (outside red lines) then the result shows a significant difference between the forecast and the actual values. This would indicate that the implementation of the guideline had significantly affected the variable under investigation. A pink arrow shows the beginning of the intervention, in January 2002.

8.3.1 Time to Extubation (extubation time)

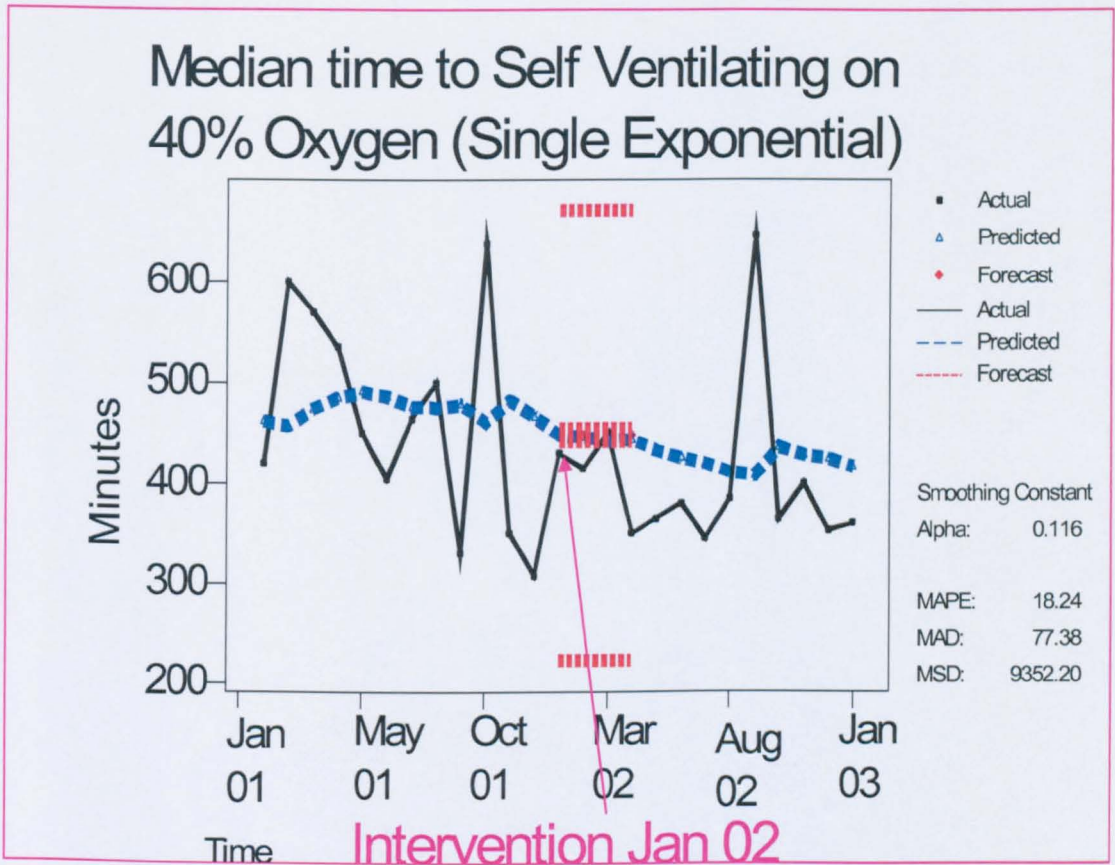
Figure 8.3.1 Median Extubation Time



There was no significant difference between the forecast values and the actual second year data for the variable time to extubation. The null hypothesis that the implementation of the guideline did not affect the time to extubation cannot be rejected.

8.3.2 Time to Self Ventilating on 40% Oxygen

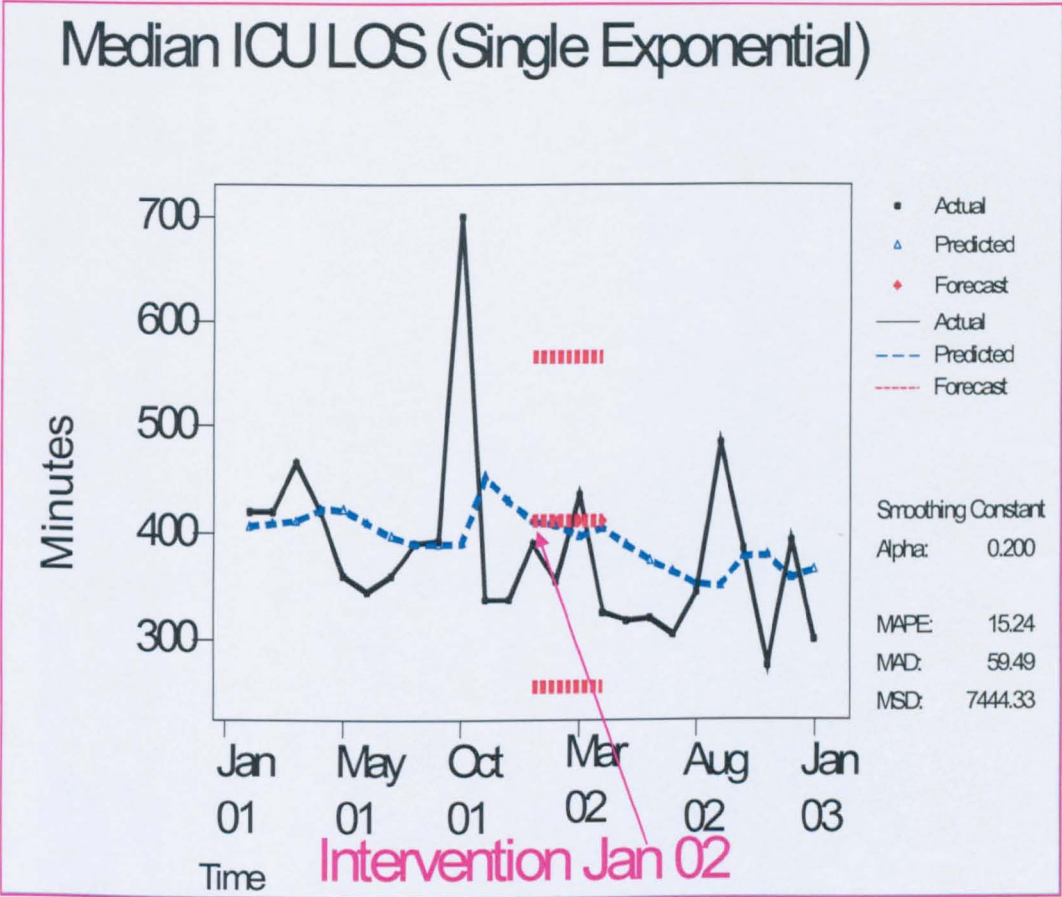
Figure 8.3.2 Median Time to Self Ventilating on 40% Oxygen



There was no significant difference between the forecast values and the actual second year data for the variable time to self-ventilating on 40% oxygen. The null hypothesis that the implementation of the guideline did not affect the time to self-ventilating on 40% oxygen cannot be rejected.

8.3.3 Time to Transfer to HDU or Intensive Care Unit (ICU) Length of Stay

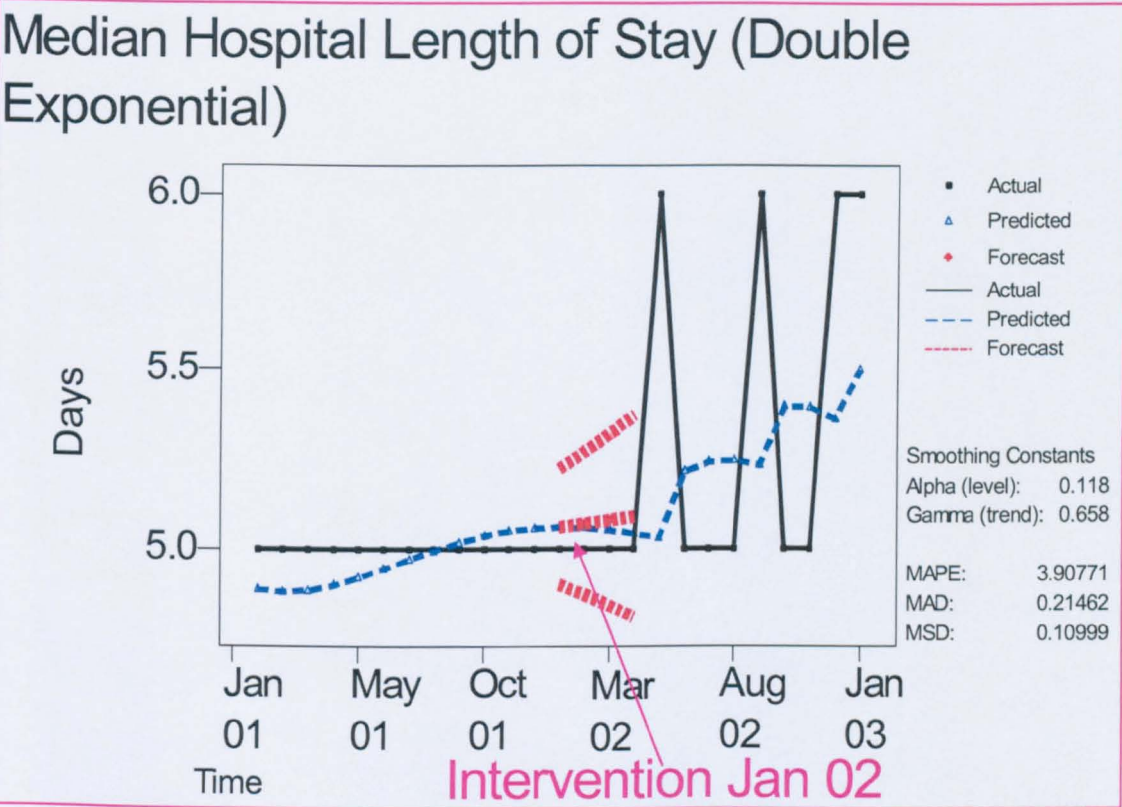
Figure 8.3.3 Median ICU Length of Stay (LOS)



There was no significant difference between the forecast values and the actual second year data for the variable ICU length of stay. The null hypothesis that the implementation of the guideline did not affect the ICU length of stay cannot be rejected.

8.3.4 Time to Discharge from Hospital or Hospital Length of Stay

Figure 8.3.4 Median Hospital Length of Stay



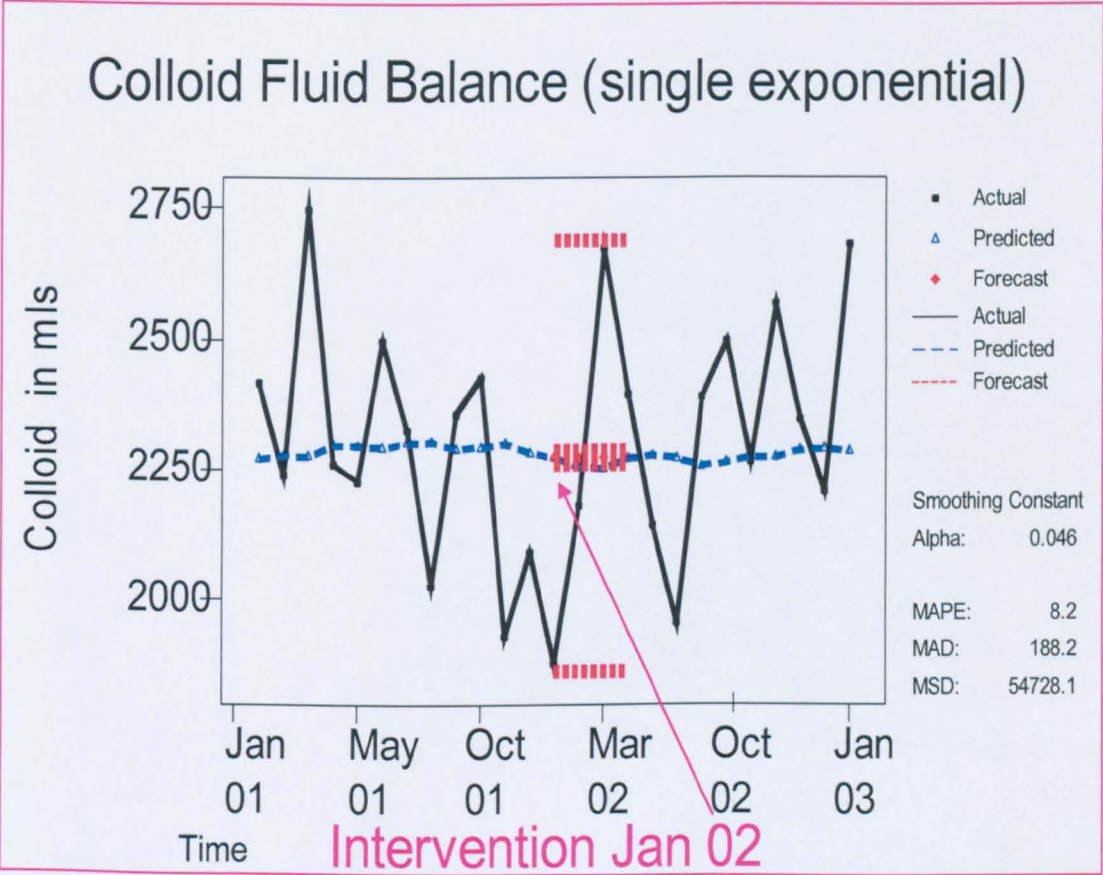
There was no significant difference between the forecast values and the actual second year data for the variable hospital length of stay. Although the results look dramatic, there is only a difference of one day between the lowest and the highest values. The null hypothesis that the implementation of the guideline did not affect the hospital length of stay cannot be rejected.

8.4 WITHIN PERSON CONTROL VARIABLES RESULTS

The results for the within person control variables, colloid fluid balance and number of arterial blood gas samples are presented below.

8.4.1 Colloid Fluid Balance

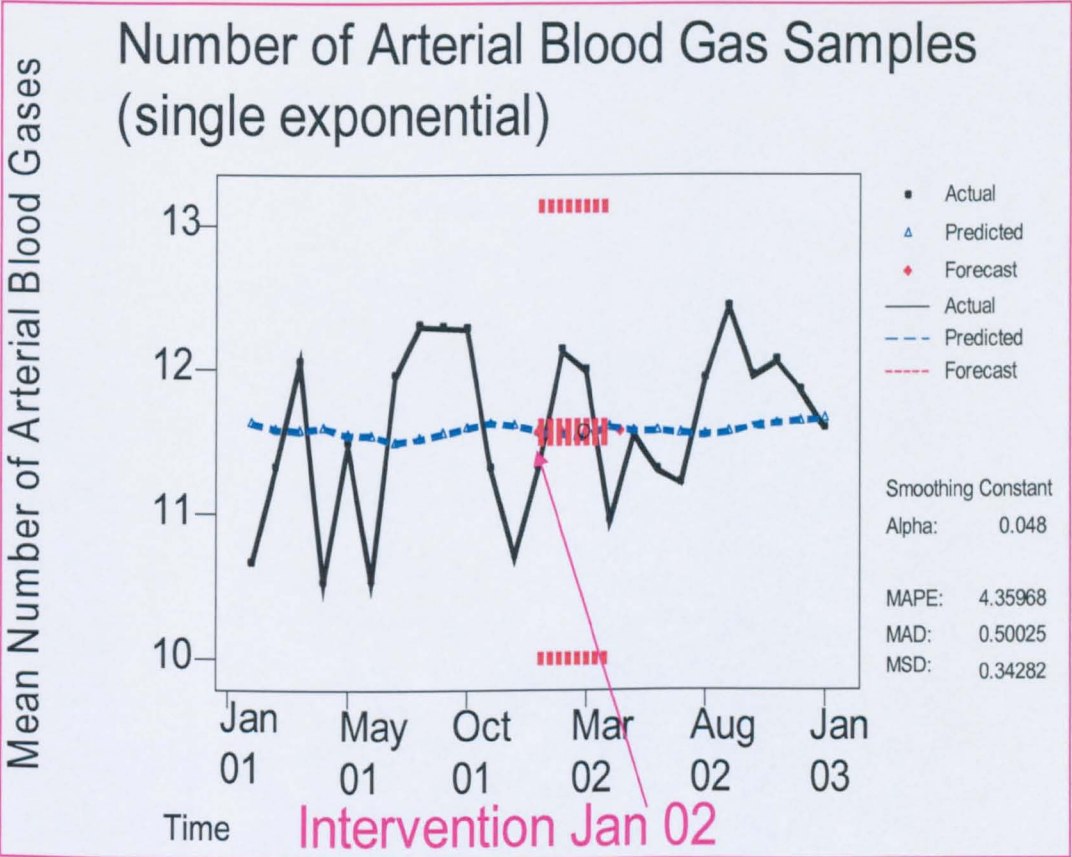
Figure 8.4.1 Mean Colloid Fluid Balance



There was no significant difference between the forecast values and the actual second year data for the variable colloid fluid balance. The null hypothesis that there was no difference between the two years in the mean colloid fluid balance cannot be rejected . This indicates that it was unlikely that there were any confounding variables affecting this nursing practice at the study site that were significantly different between the first and second years of the study.

8.4.2 Arterial Blood Gas Samples

Figure 8.4.2 Mean Number of Arterial Blood Gas Samples



There was no significant difference between the forecast values and the actual second year data for the variable number of arterial blood gas samples. The null hypothesis that there was no difference between the years in the mean number of arterial blood gas samples taken cannot be rejected. This indicates that it was unlikely that there were any confounding variables affecting this nursing practice at the study site that were significantly different between the first and second years of the study.

8.2 SUMMARY OF RESULTS

The samples for years one and two of the study were similar for most of the variables investigated. There were, however, some statistically significant differences between the samples for years one and two. These variables should not have affected the results significantly, either because the design of the study would have controlled for any impact or because the variable would not have had an effect on early extubation and the outcomes studied.

The interrupted time series analysis showed were no statistically significant changes identified in any of the outcome variables, variables time to extubation, time to self ventilating on 40% oxygen, time to transfer to HDU (or ICU length of stay), and time to discharge from hospital (or hospital length of stay). This indicates that the implementation of the early extubation guideline did not affect the outcomes studied.

The results of the within person controls increases the confidence that, had there been any impact by the implementation of the early extubation guideline on the outcome measures, it would have been detected in the analysis. There were no significant differences in the trends of nursing practice in colloid fluid balance management or arterial blood gas sampling (the within person control variables). It was, therefore, unlikely that any confounding variables, that were different between the two years, significantly affected nursing practice at the study site, including the practice of early extubation. The reasons for the guideline having no impact on the study outcomes will be explored in the discussion chapters eleven and twelve.

CHAPTER NINE

QUALITATIVE STUDY ANALYSIS

9.1 INTRODUCTION

The interviews were transcribed and analysed using the 'framework' approach (Ritchie and Spencer, 1994) described in the methodology chapter six. Three overarching themes emerged from the data: the *context* (Figure 9.1a), the *process* (Figure 9.1b) and *tensions* (Figure 9.1c). The theme is presented in the top box of each diagram. The categories and sub-categories of the theme are presented in the boxes in the subsequent rows. The lines drawn between boxes demonstrate the relationships between the theme, the categories and the sub-categories.

Figure 9.1a Theme 1: Context

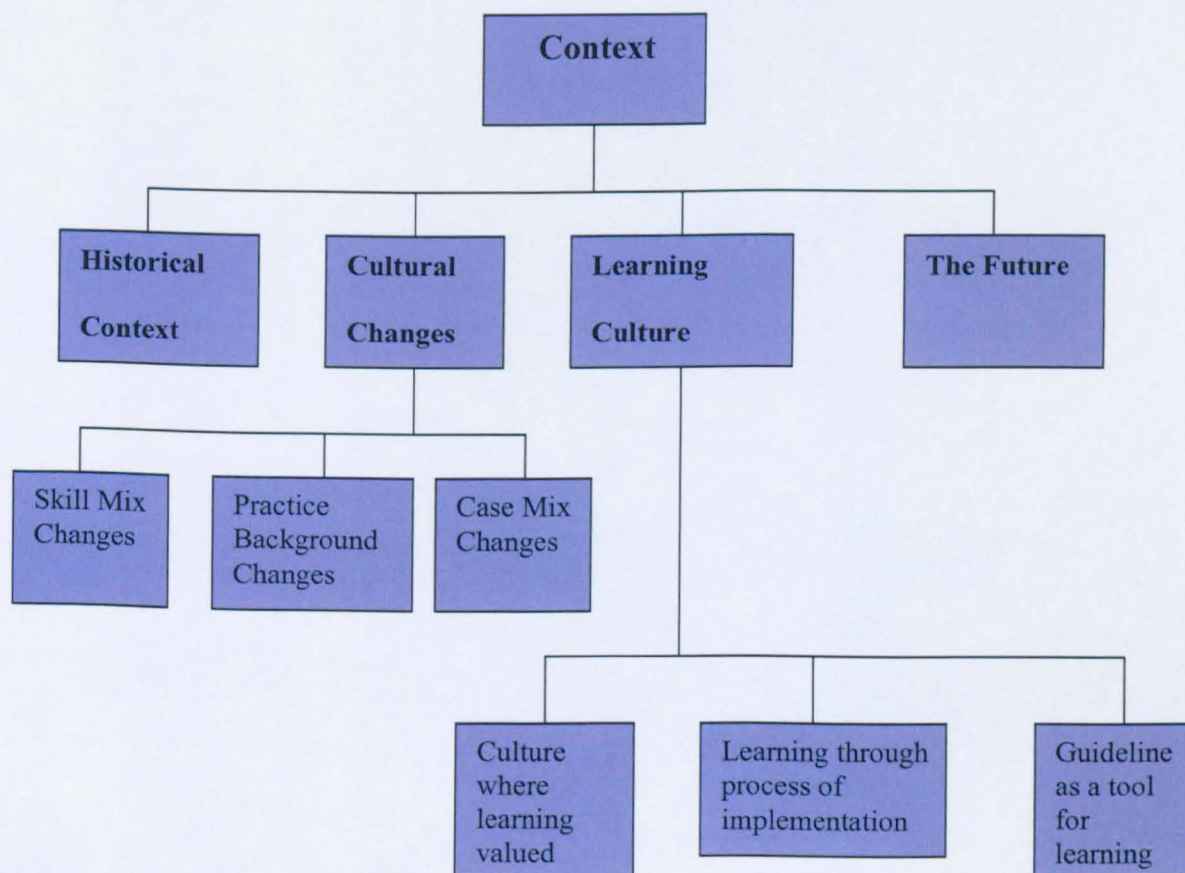


Figure 9.1b Theme 2: The Process

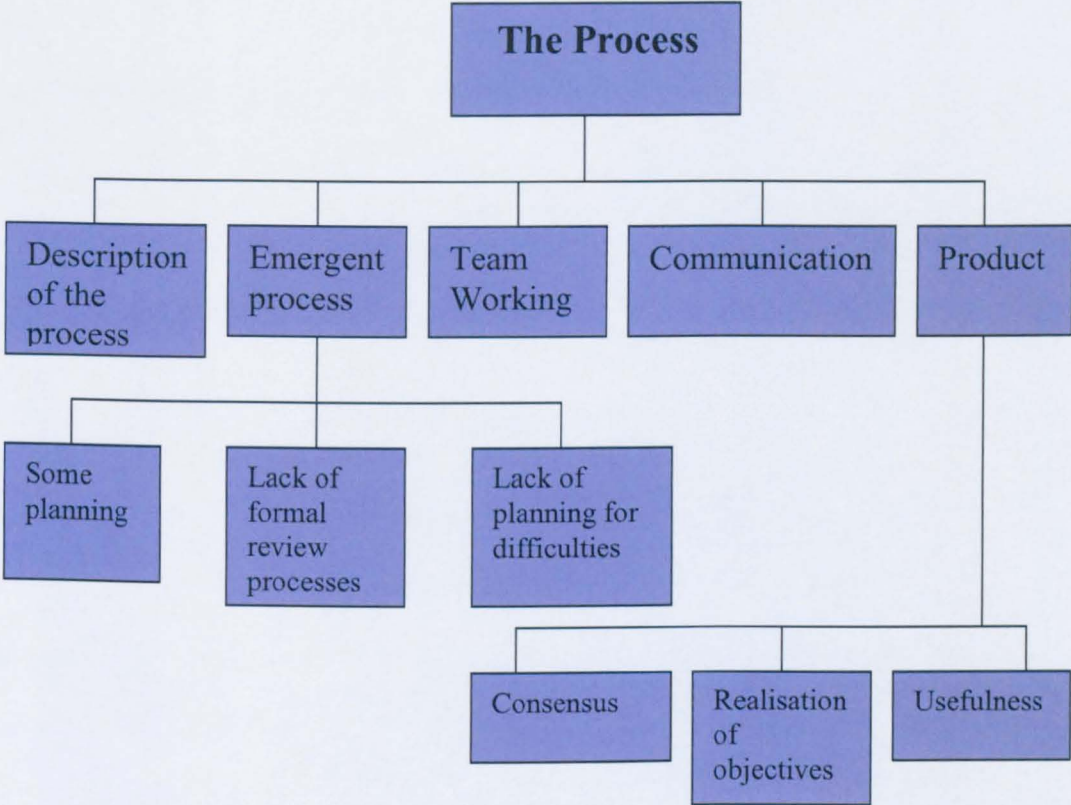
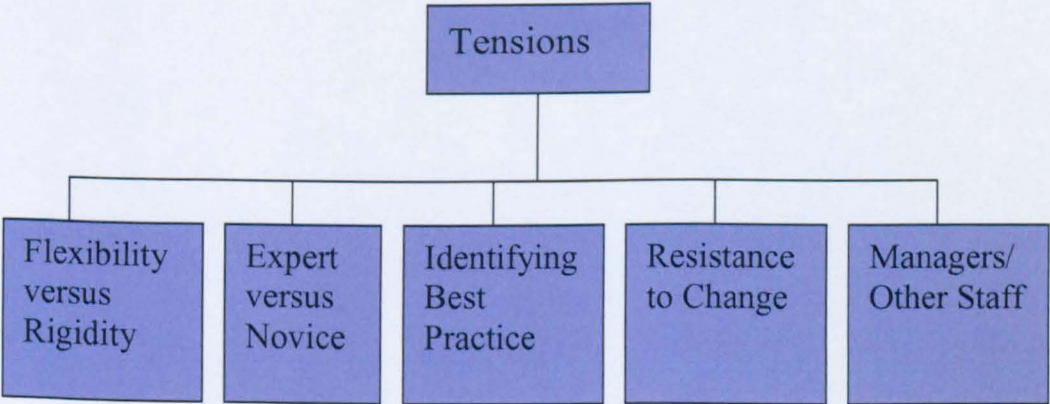


Figure 9.1c Theme 3: Tensions



The term guideline and protocol are used in this section for the clinical decision guideline the study site implemented, because the term was used interchangeably by interviewees, although guideline was the term they finally decided to use in practice.

9.2 THE CONTEXT

The respondents raised several aspects of the *context* within which the guideline was implemented. These aspects formed the categories of the historical context, cultural changes, learning culture and the future.

9.2.1 The Historical Context

Several respondents talked about the historical context in which the guideline was developed. There appeared to be an existing guideline that was not used and some respondents were not aware of its existence. One mentioned that it wasn't user friendly because it was in a paper published in a medical journal. The need for a guideline was prompted by a review of the service, the increasing importance of the clinical governance agenda within the Trust and the need to update the existing guideline. There was also a feeling that extubation times had been increasing and a guideline might help to reduce these times.

9.2.2 Cultural Changes

Several respondents commented on the change in culture experienced by the unit. Specifically changes in skill mix of nurses, the clinical background of both nursing and medical staff and a change in the management culture. Some respondents, who had been working on the unit for several years, commented that the nursing skill mix had changed with both the senior and junior clinical nurses generally having less experience than their predecessors.

It was generally considered that an increasing proportion of medical and nursing staff on the unit came from an intensive care background rather than a theatre recovery background. Clinicians' practice backgrounds were thought to influence their approach to extubating patients. This change was an ongoing process that was continuing to influence the culture of the unit.

One of the things that has impacted greatly is the skill mix in nursing staff. There are much less experienced nurses in early extubation on the unit than there were before and the senior nurses now tend to be much more from an ICU orientated background and that impacts on the extubation policy and the approach to extubation on the unit.

(Case3, member of staff)

...the other thing that will change probably is that we have more and more anaesthetically trained doctors, who have done intensive care. They will probably go more on weaning protocols because they have more experience in ICU ...whereas before it was theatre anaesthetists helping out....

and

...not going through a weaning mode (on a ventilator)...is slightly unorthodox, well for an ICU unit it would be difficult. But for recovery nurses it is absolutely the norm, ... (in theatres) they all get extubated, none of them go through any form of weaning...not even SIMV. We go straight to mandatory ventilation to breathing and as soon as patients breath on an ET tube they get the tube pulled out and ...it is far more abrupt than here. But you know both ways seem to work.

(Case 11, project team member)

Several managers said that there had also been a change in the case mix of patients. This was considered to be a possible explanation for the increasing extubation times. There was a greater proportion of more complicated cases compared with the early to mid 1990s when nurse-led extubation had been established.

A change in management was thought to have contributed to a more proactive attitude towards guideline development on the unit. There was also a feeling that the process of implementing the guideline had challenged the management culture.

9.2.3 Learning Culture

The category of learning culture emerged during the interviews. Three respondents mentioned the supportive learning environment as a positive aspect of the unit's culture.

Quite often just on the ward round or whatever...(name) often comes up with "I think we should do this and this" and if it is ...something I'm not always familiar with...I do tend to question and (name) is quite good at saying, " Oh there is this article on such a thing" and get a copy and what ever...

(Case 2, member of staff)

...the introduction of the clinical nurse specialist role for instance has had quite a big effect...because...going around questioning people and just being there as a resource as well and as a support to talk through things with the more junior nurses and some to the more senior nurses...

(Case 9, member of staff)

I think the one that I like the most is the supportiveness of the environment. I mean everyone's willing to teach you, show you how to do things. Also the resource groups I find, they are quite helpful...just the mere idea that we have a resource group that is actively looking into different issues, I think is enough to sort of motivate someone like me to keep reading...

(Case 10, member of staff)

It was clear that most respondents thought that the guideline itself had a key role in learning. There were two main ideas within the theme of learning and education. Firstly, most respondents thought that the guideline was a useful tool to help new nurses learn the skill of extubation. Secondly, the development and revisions of the guideline encouraged thinking and discussion about the practice.

(name) managed to create turmoil...(name) managed to create people to think and even if (name) hadn't done it successfully (implemented the guideline) (name) got everybody thinking about the process of extubation...So (name) got people to challenge each other about it...

(Case 1, project team member)

...it develops that knowledge base and I think the protocol gets people thinking...(name) didn't want it to be so closed, it has to be people have to go up to the co-ordinator and say as well "base deficit is such and such, can I extubate?" and it gets this sort of bouncing of ideas ...so there is learning from it as well, so that's why I think it is a great learning tool...

(Case1, project team member)

The issue of experience was raised in the context of learning a skill. Several respondents thought it important to use the guideline flexibly. When experienced nurses practised outside the guideline, this was seen as an opportunity for discussing and learning for inexperienced nurses.

...a lot of times I actually practice outside the guideline, but I can use that as a teaching tool. " This is what the guideline says, this is why it is saying this. This is where I am going to deviate from it and this is my reason for deviating". So I do think it is a very useful teaching aid.

(Case 3, member of staff)

Two respondents mentioned how nurses gain expertise in the skill of extubation. One of these respondents talked about the concepts of propositional knowledge and craft knowledge. The content of the guideline was viewed as propositional knowledge but the guideline also provided a tool for the practitioner to develop craft knowledge (i.e. to learn how to extubate through experience of the practice).

You need to rely on craft knowledge as well. So you know they talk about propositional knowledge... – this is the way we do it, these are the scientific values, but there is also this knowledge content, craft knowledge Mike Lehrer talks about... craft knowledge is knowledge that, it's a bit like intuition, "Well I know this patient can be extubated and I don't know why" ...craft knowledge...is knowledge you have picked up...and I'm not sure a junior grade (nurse) has got the capacity to have this craft knowledge yet...I think that is developed through challenging or discussing the points of the protocol and they learn from it.

(Case 1, project team member)

9.2.4 The Future

Looking to the future, one respondent commented on the need to look at the whole patient episode, not only at reducing extubation times, when considering the cost benefits of changing practice. Other respondents mentioned plans to expand the unit and increase patient throughput.

9.3 THE PROCESS

The theme, the *process*, has clear links with the interview schedule (see Appendix B), as the respondents were asked specifically about the process of implementation. The *process* of implementing the guideline consisted of a number of categories. These categories that emerged from the respondents data were a description of the process, an emergent process, team working, communication and the product.

9.3.1 Events In The Implementation Process

Respondents were asked to relate the process of implementation. Implementing guidelines was a new experience for all members of the project team. The stages in the process emerged as follows-:

- Identification of the need for a guideline
- Project group established
- Guideline developed and drafted
- Consultation period
- Teaching the agreed guideline to nursing staff
- Guideline amended
- Audit of existing practice (mentioned by only one respondent)
- Implementation
- Review and revision

Table 9.3 shows a time plan of the process.

The impetus for developing the guideline also seemed to come from the senior nurses who discussed the need to develop guidelines, identified areas of practice and prioritised which guideline(s) should be developed first. Only the nurse managers mentioned that the progress of the guideline was regularly reported on and discussed at the regular sisters' meeting, perhaps reflecting their strategic role in managing the unit.

The practice development nurse established a project group of nurses interested in extubation and a consultant anaesthetist. The project group was led by one of the nurses. The project group reviewed the literature and discussed practice. They had regular meetings to agree assessment criteria, i.e. parameters to determine a patient's readiness for extubation. The protocol, as it was originally called, was then drafted and circulated to consultant anaesthetists, consultant surgeons and senior nurses for consultation. One respondent mentioned that there was a poor response to this formal consultation.

So [name] wrote them a letter saying this is what [name] was intending doing....saying that we are going to looking at extubation and would they like involvement in it and I think one anaesthetist replied back and a verbal reply from one of the surgeons. So [name] had no feedback from people and that included nurses as well, senior nurses, one replied back...

(Case 1, project team member)

Table 9.3 Implementation of the Extubation Guideline: Time Scale

Aug 2000	Sept	Oct	Nov	Dec	Jan 2001	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan 2002	Feb	Mar	Apr	May	June													
Project group established		Protocol Developed					Teaching sessions								Protocol amended and name changed to guideline		Implementation						Review and revisions												
															Formal consultation																				
																		Informal consultation																	
															Possible Audit																				
Senior Nurses received regular updates and gave input																																			

I think that the bad point about it was I don't understand why these people didn't come forward in the beginning you know when we did it. Nobody. People had the chance to be involved - I mean when we did it we got slated.

(Case 1 project team member)

One of the senior nurses took the protocol to a departmental management meeting for approval. Teaching sessions were organised and all nurses working in the unit were encouraged to attend. When the guideline was being taught to the nurses on the unit, some people started to raise concerns and an informal process of consultation led to amendments. The key amendments made were changing the name from protocol to guideline and adding a second method of supporting patients breathing when assessing their readiness for extubation.

The guideline was advertised through the unit's communication book, (used to communicate all important information to the nursing staff). The project group put copies of the guideline by each ventilator. Posters of the guideline and the implementation date were put up around the unit. One respondent mentioned that an audit of existing practice was conducted but they were not aware of the results. Other respondents mentioned that the need for audit was something they had learnt through the process of implementing this guideline.

Several months after the implementation, the guideline was reviewed again. It appears several issues had arisen concerning certain clinical criteria. The meeting involved consultant anaesthetists and nurses representing differing views of the guideline. Some minor alterations to criteria that were felt to be hindering extubation were made. Both

versions of the guideline can be seen in Appendix D. The assessment parameters that were changed included deciding to write a guideline for the assessment of bleeding (not completed during the current study period) and the acceptable level for the base excess deficit was changed from ≥ -4 to ≥ -6 and the PH values in the respiratory assessment were removed. The acceptable amount of oxygen the patient was receiving prior to extubation was increased from a fraction of inspired oxygen (fiO_2) of 0.5 to an fiO_2 0.6. The acceptable levels of arterial blood gases were changed from a PaO_2 (oxygen level) of 10kpa to one of 9kpa and the PCO_2 (carbon dioxide level) changed from 4.5-7kpa to 4.5-7.5kpa. There were also some changes to the lay out of the patient assessment by combining the cardiovascular and neurological assessments. The ventilation settings on arrival in the unit were also changed slightly, increasing the breath rate from 10 to 12 per minute, with a reduction in the tidal volume from 10mls/kg to 8mls/kg. Instructions for action to take, if the patient did not meet an assessment criterion, were simplified by making all referrals to a senior nurse, rather than a senior nurse or cardiac surgical senior house officer or registrar.

9.3.2 Emergent Process

The process of implementing the guideline seems to have been an emergent one. That is, the process seemed to be significantly influenced by situations that arose, rather than to have followed a strictly formal and structured process. There were three sub categories that contributed to this emergent process; some planning, lack of planning for difficulties and lack of formal approval process.

9.3.2a Some planning

Most of those involved in developing and implementing the guideline seemed new to this sort of activity. They planned the process of development and implementation including

setting up a project team, developing the guideline, consulting on it, introducing it to the nurses through teaching sessions and bringing it into practice on a particular day.

Respondents were asked what the guidelines objectives were. The most commonly identified objectives were the need to standardise practice and to promote the safety of patients. Four respondents commented that different practices were confusing for new or junior nurses and that a guideline should provide clarity through standard practice. Four respondents mentioned the need for evidence based guidance. Only the nurse managers mentioned that there had been concern over lengthening extubation times and a guideline should help to challenge some extubation practice and reduce extubation times. Three respondents mentioned the objective of having written guidelines to cover staff in their practice. One of these respondents felt that the legal aspects of the guideline were not clear. One respondent, who was not part of the project team but did use the guidelines, was not aware of the objectives.

Respondents were also asked about what they felt had gone well or what had been difficult during the implementation process. Three respondents felt the process had gone well and two mentioned that the plan for implementation had been followed. This question, and one about what the respondents had learnt from the process, produced data that yielded the next two subcategories (9.3.2b and 9.3.2c) of the emergent process.

9.3.2b Lack of a formal approval and review process

The need for a formalised structure for approving guidelines was a frequently mentioned issue. A difficulty highlighted by respondents was a lack of representation of the project group at senior level meetings.

...a lot of the times it has been brought up at different meetings and this, that and the other, but there has actually been nobody from the group who developed it to be there to put you know their justification forward.

(Case 7, project team member)

One respondent felt that there had been a lack of managerial co-ordination for developments like the guideline.

If somebody in the unit knows the correct pathway and knows that we are walking down that path okay maybe we can direct, you know, people the right pathway, okay the first thing will be to identify the cycle. Okay, we must identify the area that we need first, then write down the guidelines and then after that, from there where do we channel them, which way to go. And then you can get the whole picture and it is much more productive, and then at the end of it you know everybody gets satisfaction.

(Case 4, project team member)

Linked to this view was the need to streamline the consultation process and to have an official channel in the management to approve guidelines. One respondent commented that the need for a formal management board had been highlighted by the experience of implementing this guideline. As a result a unit board to approve and monitor clinical governance issues such as clinical guidelines was being set up.

Several respondents raised the lack of a planned formal review process, including audit, as an issue. One of the most frequently mentioned things that had been learnt was the need for and value of audit during an implementation process. Audit was considered to be useful evidence for the need for change and also to demonstrate the effectiveness of the guideline. One respondent felt they had learned how to do audit as part of a project. One respondent

thought that the lack of an audit in the process was the result of a lack of support and advice from managers for the project team.

Several respondents highlighted other areas of the implementation process where they felt that more co-ordination or clarity was needed. These areas concerned risk management aspects, the legal framework and protection for staff offered by the guideline and the need to know where and how to access advice available in the wider organisation.

9.3.2d Lack of planning for difficulties

How the implementation process had been planned and co-ordinated resulted in several comments related to difficulties that arose. One concern was a feeling that time should have been taken to establish what a guideline was before going ahead with the development and implementation. This was seen as a way of tackling the problem that arose over the debate about needing flexible guidance rather than a prescriptive protocol once the project team began teaching their first guideline to the nursing staff (see section 9.4.2).

Another issue was dealing with resistance to change (this is discussed in more detail in section 9.7.4). The project team did not appear to have identified strategies to tackle such resistance in their initial plan, but dealt with problems as they arose.

9.3.4 Team Working

Teamwork was an aspect of the *process* that was considered to have been a positive experience. One respondent specifically mentioned that the project team leader had done a good job. Two respondents felt there had been good teamwork and one mentioned that the

multidisciplinary nature of the project team had been a positive experience. One respondent felt that the ability of the project team to appraise the research had been good.

9.3.5 Communication

Several respondents made comments about the importance of communication in the whole process. Views covered the need for regular multidisciplinary meetings, for the project group to be represented at all meetings where the guideline was discussed, the need for regular reviews of the guideline and the importance of consultation. There was a view that managers could improve communication with the project group.

I just think you know, that it is an awful lot of hard work and it can be fairly soul destroying when a lot of the work is just stamped on when it (the reason) is not even backed up with a good argument...or (without) just giving you a very good justification of why things need to be changed.... And the same with the minor changes with it along the way - to me that should be channelled through the people that developed it in the first place...it is their tool and they developed it and sometimes that gets taken away from the actual group of people that started it.

(Case 7 , project team member)

I think as a manager, if you put into practice different groups...and these people are developing guidelines ...to me the obvious thing is if there is issues with it or people just want to chat about it, it would always be beneficial to have somebody there that was involved in developing it in the first place. It's like if your car breaks down you know you take it to the people who know, rather than making decisions with a group of people that didn't have a lot of input into it. And I think also that has a big impact on motivation of the group to do further things.

(Case 7, project team member)

There were some comments on how to improve the guideline and its dissemination. The guideline itself lacked a proper structure, according to one respondent, because it was simply a decision algorithm and should also contain a clear presentation of the evidence and levels of evidence it was based on. Another respondent commented that it would be good to develop ways of including individual patient differences within the guideline. This respondent suggested using decision trees for working out a course of action when the patient did not meet any particular criteria for extubation. Another respondent had the idea of disseminating guidelines on the organisations intranet to improve interdepartmental communication of guidelines and to share work.

9.3.6 Product

There were three aspects to respondents' views on the guideline itself (the product); that it was a consensus document, a discussion of how the objectives were realised and how useful the guideline was to practitioners.

9.3.6a Consensus document

It seems that the guideline incorporated existing practice. No one, even those who expressed a strong preference for one particular method of practising extubation, thought they could not continue to practice as they wanted to. The discussion about changing the name from protocol to a guideline (see section 9.4.2) emphasised the value clinicians placed on not being restricted by the document if they wanted to use their clinical experience and judgement to practice outside the guideline when caring for individual patients. The result seems to be that everyone could continue to practice as they had always done, but that new nurses would now have agreed, written guidance about practising safely whilst learning the skill. The guideline was, therefore, unlikely to have much impact on changing patient outcomes. For example, several respondents reported

that reducing extubation times was one reason for developing the guideline, however changes in these times would be unlikely unless there was a significant change in practice. It should have, however, maintained the existing outcomes, particularly considering the contextual changes discussed in section 9.2.

Although some respondents felt the guideline had brought some standardisation of practice others commented that there was still a variety of practices on the unit. This last view is consistent with the desire to have a flexible guideline to allow variations in safe practice. In light of the lack of clear research evidence (see section 9.4.1) for what the safest and most effective method of assessing and extubating patients was, it seems inevitable that a consensus of local practice would be the evidence base for this guideline.

9.3.6b Realisation of objectives

Respondents were asked whether they felt the objectives they identified (see section 9.3.2a) had been met. Several respondents commented on the difficulty of quantifying the effects of the guideline. Measuring extubation times and rates of reintubation were seen as potential ways of quantifying the effects of the guideline. Two respondents felt that the low reintubation rate meant that practice was possibly over cautious. Another respondent held the opposite view and thought that low reintubation rates showed that practice was satisfactory. Some respondents commented that auditing extubation times before and after the guideline would have provided some information on the effectiveness of the guideline (see section 9.2.3b for more view of the value of audit). One respondent also talked about the value of audit to provide evidence for the need for change in practice and to assess the impact of a new practice, particularly where evidence in the literature was lacking.

I would audit practice the next time and then have evidence to say...or not evidence but at least I would have some information to say this is what we are doing. Because I am not really...I am still a bit still not a hundred percent confident with what the evidence is about early extubation and I have had to prove that I was doing this right. But I felt pressurised with people telling me that you have to prove that you were doing it right but they weren't prepared to tell me that they were doing it right. So I had to compromise...I would audit practice and then at least I would have some data.

(Case 1, project team member)

One respondent added that so many things influence extubation times there probably was not much change in the extubation times.

Whether it has actually changed the extubation times or whether it's actually encouraged or promoted early extubation, I cannot say and that need to be audited. I mean, anecdotally I can say maybe a little bit, but I doubt very much if it has made much of a difference, because there are so many other factors feeding into that (extubation times).

(Case 3, member of staff)

One respondent thought it was difficult to assess whether objectives had been achieved because of the very nature of guidance. This respondent felt the guideline's role as a teaching tool was much clearer.

It is difficult to say because we have already said that it is a guideline not a strict protocol. So at the end of the day you don't have to follow the guideline so you could say that some people are going to extubate and ignore the protocol, ignore the guidelines, so what is the point of having a guideline, but I think as a teaching tool. Yes a teaching tool is another kind of aim for the guideline. As a teaching tool I think it is quite important, especially for junior staff, you know.

(Case 6, project team member)

One respondent commented that it was difficult to assess whether people actually used the guideline, because they did not often see anyone looking at it. Two respondents felt that the lack of criticism of extubation practice by the surgeons meant that the guideline was working well.

Several respondents commented on the objective of standardising practice. Most felt that having the guideline written down had achieved some consistency in practice or standardisation for new staff, but one still observed different styles of practice

And the thing is with picking up skills from different people- I see a lot of styles there that instead of...well sometimes they confused me more than they help me. I am saying why did she do this when yesterday somebody showed me it's a different thing.... I can still see different styles out there. And it is probably individual preference but for someone who is really starting I don't think that is helpful.

(Case 10, member of staff)

Linked to this, several respondents thought it was valuable to have the guideline for new staff when they were learning the skill of extubating patients. One respondent had had feedback that the junior staff liked having the guideline. However, it seems that the written guideline may not have completely resolved the issue of confusion for inexperienced staff created by different ways of practising.

9.3.6c Usefulness of the guideline

All respondents made some comments on how useful the guideline was or how they thought it was used. Two major ideas emerged from these comments; flexibility of the content and use of the guideline and how the guideline was used in practice. Most

respondents emphasised that it was important to have a guideline with the flexibility to enable clinicians to respond to different clinical situations and also for the guideline to encompass alternative methods of practice. It was also considered important to use the guideline flexibly too.

So it's the chicken and egg thing again, it's like you know the person who is looking after the patient definitely okay yes, he says that the protocol says 100mls per hour bleeding is okay. If more than a 100 mls per hour bleed, then you don't have to extubate. But here you know the patient is only about 80 mls but your guts are telling you know, no point extubating because he is going to bleed, but the other person who is wanting you to extubate the patient says, "But this is what the guidelines say". So it is really – it creates a bit of frustration or a bit of friction there when you come to practice...if you are the kind of co-ordinator [nurse in charge of the shift] who really abides to the rule a is a, b is b, white is white, black is black, okay then you are going to cause a lot of friction.

(Case 4, project team member)

...I think it is quite important that we don't treat it as a strict, strict dictatorial kind of framework that we have to follow.

(Case 6, project team member)

One respondent felt there was a possibility that new nurses used the guideline too rigidly.

How nurses used the guideline and how it became incorporated into their practice was also discussed. Experienced nurses had tended to compare the guideline with their existing practice and the fact that it was for guidance made them confident they could practice outside it if necessary. They commented that they did not look at the guideline as it was already in their memory, or part of their knowledge base.

I think probably with the more senior members of staff, it is not that we don't use it because I think we kind of used our own guidelines in our heads like we have been for ages, but I think you know, like it says it is only a guideline and we can go away from it if need be.

(Case 5, member of staff)

I think the physical meat of the guideline is kind of ingrained in some people's kind of heads, so you do ...at the back of your mind you are kind of thinking through...I think sometimes people do extubate without kind of following it, you know the patient wakes up and wants the tube out so they take the tube out but I think part of that is kind of relying on that nurse's own intuition and drawing on, drawing from their own experience which I think is something quite valid.

(Case 6, project team member)

Respondents also commented on the process of inexperienced nurses learning the skill of extubating patient using the guideline. It gradually became used from memory as the nurses gained experience.

When...I could start...looking after patients on my own, there are times when the guidelines are very, very useful, say I got a very straightforward patient, but if there is some glitches ...along the way...sometimes I want to tell my senior...but of course I have to tell them because I am still building up my confidence and I don't want to contribute to problems... the guidelines say ask the opinions of the more experienced...

(Case 10, member of staff)

I think they [experienced nurses] use it but I'm not sure whether they use it, use it because ...it's already ...part of their practice. I mean let's say for me, okay, extubation protocol, along this is the way I extubate patients and I know ... I roughly know what's written on it anyway...I don't have to memorise it ... two of the methods I use to extubate patients is on the guideline so for me it is not a problem."

(Case 4, project team member)

One respondent commented that the more experienced a nurse became the more likely they would feel confident to take risks.

we have to learn through taking risks, but we are not talking about risks that could kill somebody but we are talking about safe risks and that is how you learn and that is how you develop so it is taking safe risks which obviously you can't do if you are inexperienced and on your own. But you can do if you have got some support.

(Case 2, member of staff)

Most nurses felt that the guideline was useful for new and inexperienced staff to use and use as a basis for discussion with their more experienced colleagues. This was because the guideline breaks down the areas of patient assessment and encourages discussion with other colleagues

...the protocols are fine. I mean it is just that it alerts you to the assessment areas that you need to look into before you decide on extubating patients...

(Case 10, member of staff)

I think it is good for the junior nurses in a sense that if you have no idea of what to do by reading it you know, it will probably give you a step by step guide. After that probably if they want to know more they can always discuss it- use it...like a guide for them to ask or prompt them and talk with things that they are not sure.

(Case 4, project team member)

One respondent felt that practice was passed on more verbally than by referring to written guidance. Two respondents commented that senior nurses could still override junior nurses' decisions, even when the junior nurse had based the decision on the guideline.

9.4 TENSIONS

The process of implementing the guideline raised some challenges. A number of specific issues raised *tensions* that had to be worked through during the process. These were: identifying best practice when there was a lack of research evidence, the need for flexibility versus rigidity, the needs of the expert versus the needs of the novice, resistance to change and differences in the managers and other staffs views of the process.

9.4.1 Identification of Best Practice/Evidence Base of the Guideline

The development of the guideline seems to have been a new experience for those involved in the project team. One respondent felt that the process of implementation had not drawn on any evidence about guideline implementation or from the management of change literature. This indicates that the implementation process probably emerged from getting on with the project, rather than the project team clearly articulating and using evidence about implementing guidelines to make a detailed plan of the process. This also fits with some of the views expressed about the lack of planning for difficulties (see section 9.2.3d).

Respondents were asked for their opinions about the evidence base for the guideline. It became clear that different respondents had different levels of awareness of the evidence base of the guideline. Views ranged from the assumption that the guideline was based on research to the view that research in the area is poor and it is difficult to control all variables for cardiac surgical patients in order to get high quality research evidence.

...but I'd hope it is evidence based because I know some of the people that were involved in its formulation did dissertations or might have examined lots of the literature, so I hope that it does follow their kind of recommendations.

(Case 6, project team member)

...I think the fact that there isn't any research out there that says that putting a mask over a tube is bad for you or that ASB [pressure support mode of ventilation] is bad for you, has lead to us have this doubled branched thing...

(Case 9, member of staff)

...there has been very little evidence that I am aware of that shows one ventilatory mode is particularly better than another and I mean there are so many variables when you are extubating a patient, you know, who has had cardiac surgeries. There are so many reasons why they may have a fast heart rate or be hypertensive or hypoxaemic and I think probably the method in which they pull the tube out is pretty minor - has a minor effect...

(Case 11, project team member)

Respondents who had been involved in the development of the guideline expressed various views about its evidence base. Three respondents felt that there was no evidence to support either method of supporting breathing while assessing a patient's ability to breathe for themselves. (The two methods were using a pressure support mode of ventilation,

equivalent to spontaneous breathing and putting an oxygen face mask over the end of the endotracheal tube). Another respondent was uncertain about the strength of the evidence. One respondent explained that the assessment criteria had been based on protocols from published research that shows that early extubation is safe. They felt that the second set of revisions to the guideline was made because of problems with some of the criteria identified over the first six months of using the guideline. One respondent commented that the guideline contained a lot of individual opinion as well as not being based on strong research evidence.

...I think that on the whole you know for this unit, you know, it has turned out you know to be a good guideline but at the same time I think there is a lot of individual opinion in there as well that may not be particularly evidence based.

(Case 7, project team member)

Another respondent had wanted their way of practising to be included in the guideline as it was based on years of successful experience. One respondent summarised by saying the guideline was a combination of what was read in the research literature and clinician's experience.

The lack of evidence for the best method of supporting breathing while assessing a patient's readiness for extubation appeared to leave room for individuals to insist on their way of practice being included in the guideline. The revisions to the guideline also seemed to be based on local practice experience rather than research evidence. One respondent commented specifically about the lack of high quality research.

ICU research in general is poor, badly carried and there is not very, enough of it around, so it is very, very hard to look specifically at ICU and also because you can't always look at our patients as being ICU patients even the research that comes from ICU may not necessarily be applicable to our type of patients...

(Case 11, project team member)

Respondents who were not involved in the development and implementation of the guideline had a range of views about the evidence base of the guideline. None articulated the issues that the project team respondents had highlighted. Most were not actually familiar with what research had been used and they relied on their colleagues in the project team to ensure the evidence base was sound. One respondent gave the reason for relying on colleagues in the project team to ensure a sound evidence base as that there is too much evidence to wade through for each aspect of practice for each individual clinician to be able keep up to date with everything. Two respondents commented that they had been told the guideline or the revisions had been evidence based.

9.4.2 The Need for Flexibility Versus Rigidity

Seven of the eleven respondents commented that they thought it was important that the guideline was used flexibly. A guideline that was responsive to clinical differences in patients and clinicians' different practice preferences and experience was considered important. Rigidly following a prescriptive guideline was seen as something to discourage. When the guideline was first developed it was called a protocol, but the name was changed to guideline to promote the idea of flexibility. When the protocol was taught, some nurses seemed to have raised concerns about the protocol. Views varied on this point. Some respondents felt that it was being seen as too rigid and found resistance from colleagues if they wanted to practice outside the protocol. Some respondents felt that a second option was added to the protocol because senior staff wouldn't support the protocol unless it was

included. The result of this discussion period seemed to be that the name was changed from protocol to guideline, to encourage flexible use and a second method of assessing patients was added.

The importance of encouraging critical thinking and discouraging blind following of the guideline was raised. This links to the category of learning culture, from the theme of *context*, that seemed to have been highly valued on the unit. One respondent felt that increasingly, some nurses wanted more prescriptive instructions from doctors. This was seen as a backwards step from nurse-led practice. However, balancing the demands of increasing the scope of nursing practice and providing documentary evidence of practice was seen as a tension that was influencing this trend.

...I firmly believe in a multidisciplinary approach... and I think there is absolutely no reason why experienced nurses shouldn't be able to make those sort of decisions ...I have had recent complaints from new nurses saying that...the doctors aren't prescriptive enough in what they say, they want more parameters written and to my mind that is going backwards and that's taking a very medical model onto the unit there and I would be unhappy about that...

(Case 11, project team member)

In a way it might be something about government – in a way it could be more about documenting everything so you can prove you said that, well not quite prove... Well its like being seen to be doing things. Things that you used to do instinctively now this is no longer, you have now got to make a real effort to actually show that you are going to be doing it.

(Case 11, project team member)

The debate over which method of supporting breathing while assessing a patient's readiness for extubation was discussed by several respondents. One explained that the

project team felt that because there was not much evidence for the best method of supporting breathing while assessing a patient for extubation, the safest method was to use a pressure support ventilation mode. It was considered a safer option for junior nurses who did not have advanced skills. Another respondent commented that the use of placing an oxygen face mask over the end of an ET tube (face mask option) needed clinical skills which come with experience.

You are not looking at every number because you are just getting a feel for it, and a lot of it is, what you can't put into an algorithm is clinical experience. I mean...and to a certain extent that's why the old method (face mask option) works because it was done by experienced staff and probably relies more on the clinical experience than the weaning protocol because the weanings are probably more structured, you can measure more, you can measure the tidal volumes (ventilator gives figures for such readings) and things like that.

(Case 11, project team member)

This respondent also held the view that both methods end up with the same result and that the two options had been included to accommodate different practice preferences.

Linked to the idea of advanced skills was the view of one respondent that the use of the face mask option would get nurses to recover patients more actively and reduce extubation times. Another view was that using clinical assessment was a better way of assessing patients rather than relying on numbers on a machine.

if they [the patient] are on pressure support [ventilation mode] or they are on a mask they can present differently, their breathing pattern, the rate, just by looking at they are struggling or are they not struggling, how are they moving their lungs, which can be difficult to assess if they still get that little bit of extra support from the ventilator...I feel much more comfortable looking at my patient on a face mask, than I can actually really see what his breathing pattern is doing. The issue of, with [pressure support] you have got ...values you can read, tidal volume etc. to me is not necessarily a very important aspect when you want to extubate a post surgical patient that doesn't have any lung problems and I think – you want to know that your patient is breathing adequately and that he is having adequate gas exchange but a minute volume, or a tidal volume per se to me can be pretty meaningless for most surgical patients.

(Case 3, member of staff)

In spite of all the discussion during the implementation of the guideline, several respondents thought that the pressure support option was used much more frequently than the face mask option. Some respondents suggested this preference was probably linked to the change in culture (see section 9.2.2) on the unit because more nurses and doctors now came from an intensive care background, rather than from a theatre recovery background. In intensive care weaning patients using a variety of ventilation modes would be usual practice, whereas in theatre recovery units patients would usually be extubated as soon as they could protect their own airway following surgery. This is because recovery patients would be unlikely to be ventilated for any lung pathological processes, as would often be the case for ventilating intensive care patients.

9.4.3 The Needs of the Expert Versus the Needs of the Novice

One of the guideline objectives, mentioned by four respondents, appeared to be promoting a standard practice to prevent confusion of junior staff when learning the skill of extubating patients. However, promoting a standard practice seemed to have generated the

debate about the need for a flexible guideline to enable staff to use their clinical judgement (section 9.7.2). The needs of some experienced staff seem to have been addressed by a second practice option being added to the guideline. Some respondents felt some experienced staff were reluctant to change their practice to facilitate having a standardised guideline.

Because senior members of staff wanted it [the face mask option in the guideline] included. And they wouldn't teach that protocol without that being in it. Because it was their way of practising.

(Case 7, project team member)

In contrast some of the experienced nurses felt it was important to have both practice options and that their experience of practising safely using an alternative practice option should be respected.

The second arm of the choice, where somebody can go onto [pressure support]. I was very adamant that my way of practice has always been put them on the mask and I was being questioned by very junior members of staff, "but this is not in the guidelines so why are you doing it and we are not going to do it" and I felt very strongly that actually it should be the preferred way of doing it, although I was – I felt happy to be flexible enough that there can be a choice...

(Case 3, member of staff)

The issue of meeting junior staff's needs in learning the skill of extubation is linked to how the guideline was used as an educative tool (see section 9.6.4).

9.4.4 Resistance to Change

Resistance to change was discussed in several ways. The majority of respondents commented on how change challenged individuals. One respondent thought that the

guideline had caused turmoil but it had successfully made people think about their practice.

One respondent found that people's resistance to change was the biggest problem encountered during the implementation

I think by far the biggest problem is just resistance to change. And like I say that is at all levels – from consultants...I mean I still get it from consultants now, you know, “lets get rid of that [pressure support option] and you know, so that is by far I think the biggest issue.

(Case 7, project team member)

...it has been one hell of a learning curve to actually see how resistant people can be to change, because although you do it – and god knows how many modules and essays I have written on resistance to change – until you are actually in that situation you don't actually realise how resistant people can be and how very difficult it can make things...

(Case 7, project team member)

This respondent felt that the most resistance came from the most experienced people.

The biggest, by far the most resistance has come from the more definitely more senior people. I don't know anybody you know of junior level or an equal level that has resisted it in any way.

(Case 7, project team member)

Another commented that their way of practising had been challenged by junior staff, who would not see the value of different practices. The respondent felt that the alternative method of supporting breathing whilst assessing the patient for extubation should be included to help diffuse this issue.

One respondent commented about the impact of an individual's willingness or reluctance to use the guideline on the implementation.

I think about the usage of the protocol [is about] other factors...I think it very much depends on individuals if they are reluctant to use it. As I say for me, may be if my practice is different from what is written there, I might be a bit resistant to try it as well.

(Case 4, project team member)

Four respondents made comments about the impact of personality on the implementation process. One respondent summarised this issue by commenting that the conflicts in the implementation process were more to do with personalities than any thing else.

It seems to be that both methods [face mask and pressure support] end up with the same result with the tube being taken out of the patient. And you know done safely and in a manner that I think is perfectly satisfactory. I mean if there has been conflict it has probably been more personality and, I mean there isn't much I can do about that.

(Case 11, project team member)

Two respondents commented that the reason a second option was added after the formal consultation period was because senior nurses would not support the guideline unless the second option was added.

One respondent commented on how difficult it was to deal with people who did not raise any concerns when consulted formally, but then took things into their own hands later on.

That came about from disagreement on the parameters. And I think I felt that in [name's] role...allowed it to be taken away from [name] by another person, who had definite ideas of what it should be... and this was taken up with an anaesthetist and luckily the anaesthetist they didn't change many of the parameters...So that was good. I think that the bad point about it was, I don't understand why these people didn't come forward in the beginning you know, when we did it...People had the chance to be involved- I mean when we did it we got slated..."

(Case 1, project team member)

One respondent commented that they felt pressurised into providing evidence for their preferred option, by those with another preference who were not prepared to provide evidence for theirs. Another respondent commented that people had strong views of best practice and thought some were telling other clinicians not to use the alternative option when two were included in the guideline.

...Some people are very anti the mask over the tube way of assessing a patient and I have actually heard somebody say to somebody, "you are not allowed to do that", which I found very interesting, even though it was on the guideline that you are and it was actually quite a senior member of the team...but those...are just individuals coming out and doing things like that. And you are always going to get that..."

(Case 3, member of staff)

Some respondents felt that some individuals were resistant to taking on a different practice in spite of evidence to support the change.

...that got challenged by colleagues on their own, "Oh this isn't right" and "I'm like well, why isn't that right?" And the person that did it with me, we did a literature search and people weren't taking on the literature, "Well we don't want to do that and that is it."

(Case 1, project team member)

...just the fact of ongoing delays and changes and things like that and then I think you end up having a guideline that just reflects individual people's preferences rather than you know an actual sound sort of generic guideline...it has turned out to be a good guideline but at the same time I think there is a lot of individual opinion in there as well that may not be particularly evidence based.

(Case 7, project team member)

Others felt they could defend their practice, which was based on years of experience, and show the benefits of it.

...I felt very strongly I could defend why I was doing and justify my actions, and that I wanted to teach people the benefits of doing it the other way as well as [pressure support], I was getting so much resistance because it wasn't on the guideline that it became clear and following discussions with the senior nursing team I insisted that I cannot participate in this early extubation philosophy if I cannot function in a way I think we can achieve that....

(Case 3, member of staff)

It seemed that there were different views about what practice the research evidence supported and that presenting research did not always persuade people to change practice. One respondent commented that the final guideline was a reflection more of individual preferences rather than being based on sound evidence.

One respondent found it challenging to have to compromise their views when they were not certain that other method of practice was based on strong evidence.

...having to be so diplomatic and trying to – you know and having to compromise sometimes when you don't necessarily think that it is the right thing – not the right thing to do, but you know when you query how much evidence other people got that are putting their opinions in.

(Case 7, project team member)

Another respondent felt that the guideline was sometimes used as an argument to defend a position.

I think the only things that I see is people use our protocol as an argument, you know arguing point, especially when it relates to extubating people...

(Case 4, project team member)

They felt that the discussion and challenge raised by the guideline was good but that sometimes it had been used more as a weapon than a point of discussion.

The promotion of discussion and challenge I think is a good thing... if people use it correctly, it is like a weapon, it is like a knife okay, it is a good thing that you know. I really appreciate the person who invent the knife because it helps us to cut things easily, but on the other hand people, laying on the wrong hand and people use it differently then it is a disaster, so it is the same thing here I think the protocol- yes it promotes a lot of you know reflection and critical thinking you know but on the other hand people must be aware that they can use this protocol for argument...

(Case 4, project team member)

Several respondents raised the issue of a challenge to professional boundaries. On the whole, these comments were linked to a change in the medical staffing mix rather than the actual guideline implementation. It appeared that nurse-led extubation, although it had been established for about ten years on this particular unit, was a surprising practice for some new doctors and that some new nurses needed encouragement to take on this role. Some respondents felt that this resulted in some negotiation of boundaries.

I don't even know if the anaesthetic [registrars] are aware that we actually have an extubation guideline, because I think they all tend to just kind of use their own preferences, their own practices, so we probably need to make them aware that we do have this guideline and that it is a unit guideline, it is not for nurses, it is a unit guideline and if they want to step outside of it then they need to be prepared to be challenged about that by whoever, really...I think the major thing is we need to get across to the nursing staff that that is actually their decision, they have got a guideline there to help them make that decision, It's their decision.

(Case 9, member of staff)

In contrast, one respondent felt that the new doctors had had little impact on extubation of uncomplicated patients that the guideline was developed for, because it was a nursing practice.

...recently we've got all new anaesthetists and obviously they have got their own ideas but I mean to be quite honest it is such a nurse-led unit isn't it that the anaesthetists don't really have...the consultant anaesthetists are rarely around when we are doing it and we really only get them involved if we run into problems and then you are totally off the guideline anyway aren't you ...

and

they [anaesthetic registrars] obviously know that it is very nurse-led and no they just seem to let us get on with it and if we need them then they will come and help us regarding you know extubation and things, but that would only be if they were off the guideline...

(Case 5, member of staff)

9.4.5 Differences in the Managers' and Other Staffs' Views of the Process

The managers understandably appeared to take a more strategic role in the process of implementation than more junior staff, but there were differences in views of their respective contributions to the process. For example, as mentioned in section 9.3.1, only the managers mentioned that the progress of the guideline's implementation was regularly discussed at senior nurses' meetings. In contrast other respondents commented on the need for members of the project team to be included in all meetings where the guideline was discussed (section 9.5). This could indicate that although the guideline was discussed by senior nurses members of the project team may have felt excluded from these discussions and that the managers may have been unaware of this because it was not raised as an issue for them.

Some managers also seemed to think that the project group could have communicated better about the project.

I don't think it was actually... it really wasn't launched – if you know what I mean and I think sometimes these things – there almost needs to be a bang to say 'it's here and this is what it is and this is what it is about' and 'this is going to be the implementation date' and then 'these are going to be the training days' so you need to...I think it was done in a very gentle gradual sort of way and I think because of that some people weren't aware that it had been implemented...

(Case 9, member of staff)

There were also differences of opinion about the consultation process. One respondent commented that a number of people felt they had not been consulted during the development process, whereas other respondents had been disappointed at the lack of response to their consultation and the informal consultation that resulted once the guideline had been taught to the nurses.

...and I think with all these things other people who felt that they should have been involved and that they should have been able to look at the guideline before it was put out there feel that they weren't actually as involved as they would have liked to have been, so almost it was kind of implemented by stealth, I think some people seem to feel.

(Case 9, member of staff)

[the project group] put it [the draft guideline] out to surgeons and anaesthetists to look at for their comments...[name] wrote them a letter saying we are looking at extubation and would they like involvement in it and I think one anaesthetist replied back and a verbal reply from one of the surgeons. So we had no feedback from people and that included nurses as well, senior nurses, one replied back...

(Case 1, project team member)

The reasons for such differences were not explicit in the data. It may be that there was a lack of communication between the project group and the managers so they were unaware of each other's roles and discussions, or it may have been a reluctance to understand each other's roles in the process. What does emerge was that a number of the staff felt that the managers could have done more to enable the process of implementation.

...as these things have to go through senior staff I don't know whether there could be an improved way to channel that through so that it didn't take such a huge amount of time between actually finishing it and getting

it out into practice. I think more support to do these things, like more time, that you can actually be given time to implement these things in and instead of rushing round trying to do everything in your own time if you are allocated time to go and do literature search and things like that and of course the quality of it could potentially be better...

(Case 7, project team member)

[name] was criticised that it was taking too long. On the other hand the reason why it took too long was because people kept changing, management from the top kept on putting something their cogs in...a spanner in the works..."

(Case 1, project team member)

The managers also recognised the need to improve the process of implementation and were setting up a clinical governance board as a forum where developments, such as guideline development, could be approved and reviewed.

Two respondents felt that the established way of implementing change was a top down approach. One commented that this led to a lack of change.

But if everybody is just doing work that the top pass down "you do this and do that" and don't see what they need to see and consider other aspects then I think probably ten years down the road we are still doing the same thing...

(Case 4, project team member)

Another respondent felt that the guideline had been implemented using a bottom up approach, which had challenged the previous top down approach.

...I think a lot of change has happened before ... from the top [name's] philosophy is from the bottom and that is what [name] tried to do... involved the people are at the working level to implement the change and... "well I have got the knowledge. Why are they doing it?" and that did come across with certain—or I know one person within the group had done their dissertation on early extubation but that knowledge was dismissed and the other person's knowledge was dismissed as well in the group, so I think that was hard to deal with. But [name's] philosophy is that you... can't change practice from the top, but I think now people are seeing that and I think it has been devolved [sic] from the bottom now...

(Case 1, project team member)

9.4.6 Time

Another area of challenge mentioned by two respondents was time. One felt that it was important not to rush a change process.

I also think we try and introduce change so quickly sometimes and I don't think we did with this. Cause I think it went on and seemed to follow really good process but often you do find that if you say you are going to do something people expect it there the next week or something, or the next day and that is often when they don't work properly because you haven't thought it through properly, people have not been brought on board with it and it soon falls flat then. So I think it is important that people stick, plod along at it and don't feel under pressure to rush it through.

(Case 2, member of staff)

The same respondent also commented that the guideline had taken a long time to implement because people's time was pressurised and other work demands often caused delays and that sometimes projects never get completed. Another view, concerning time,

was that the bottom up approach of implementation had taken time because of the challenge it presented for the managers.

9.5 THE ROLE OF THE RESEARCHER/CLINICIAN

The researcher was also a clinician at the research site. In order to explore the effect or impact of the dual role on the research and on the guideline implementation all respondents were asked for their views. The researcher also kept a reflective diary. These two sources of data were used to facilitate reflexivity in this section of the study (see chapter six for discussion of the researcher practitioner role and reflexivity in ethnographic research). In her clinical role the researcher was involved in discussions about the development of the guideline. The researcher was not involved in driving the implementation process forward. Her only role at this stage was assisting with some of the teaching sessions for the nurses. This level of involvement meant that the researcher felt she did not experience a role conflict when asking respondents for their views of the implementation process. She did not experience their responses as a criticism or particular praise of her own work. She felt comfortable exploring different issues raised by respondents.

The analysis of these two sources of data identified three themes, *areas of potential influence* (figure 9.5a), *presenting a balanced perspective* (figure 9.5b) and *implicit knowledge of the setting* (figure 9.5c).

Figure 9.5a: Areas of Potential Influence

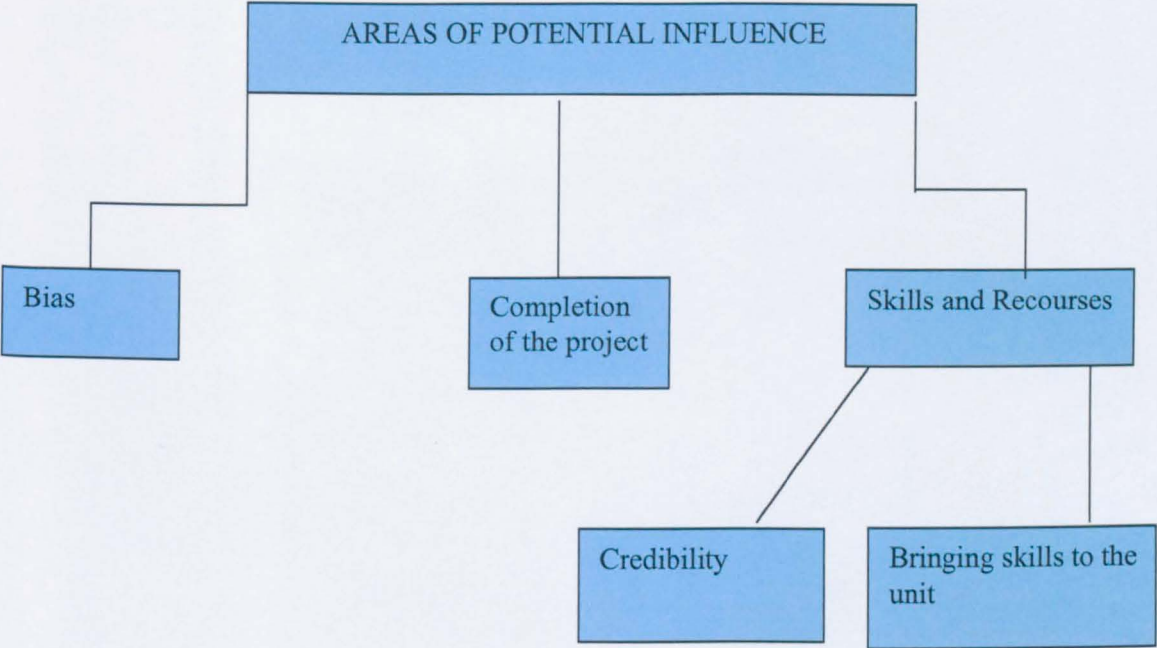


Figure 9.5b: Presenting a Balanced Perspective

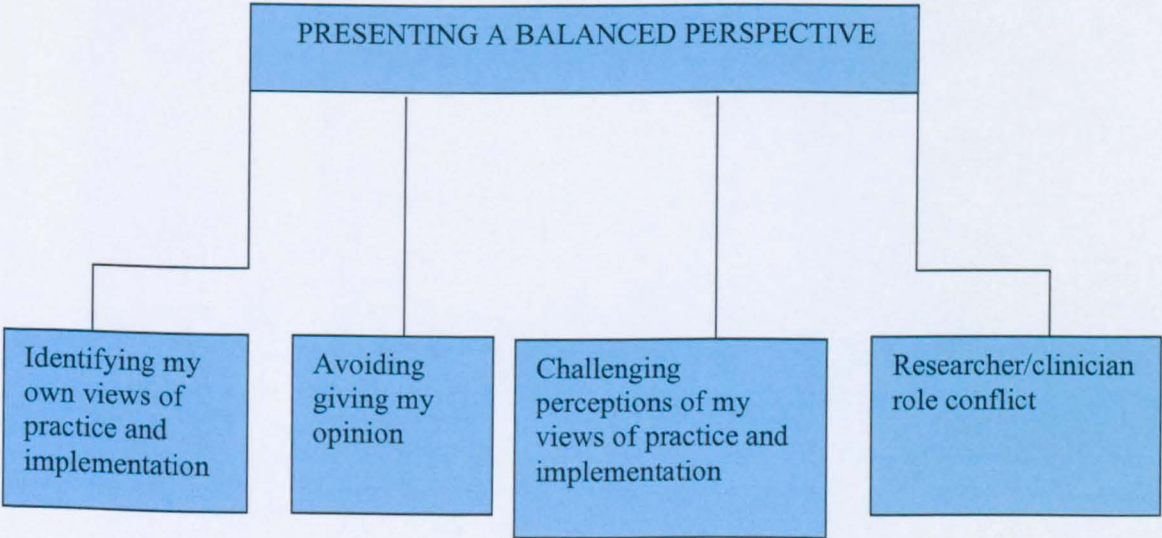
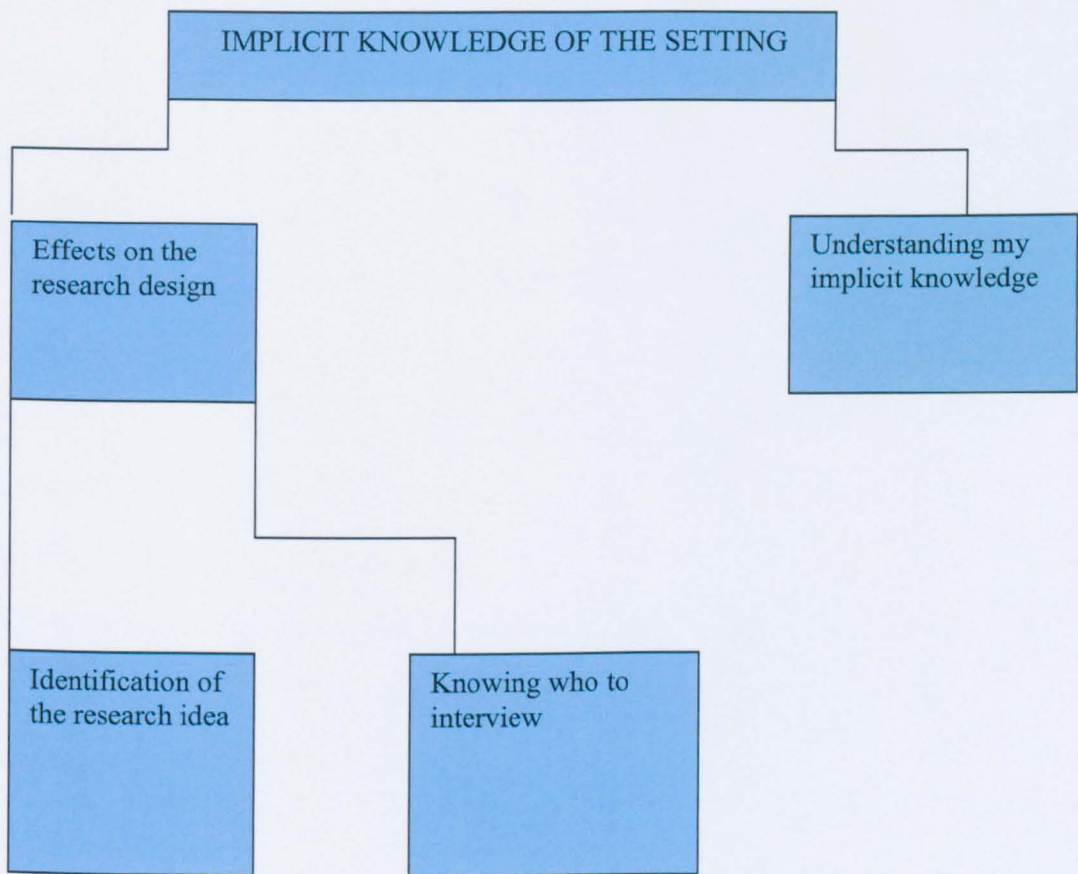


Figure 9.5c: Implicit Knowledge of the Setting



9.6 AREAS OF POTENTIAL INFLUENCE

The theme of *areas of potential influence* emerged from the respondent's data.

The issues raised by respondents, within the theme, formed three categories. These concerned the possibility of introducing bias into the research, the researcher's skills being seen as a resource to the unit, making the research credible because it was done by a

clinician, and raising interest in early extubation which may have influenced the completion of the implementation process (the project).

9.6.1 Bias

Six respondents commented on the possibility of the researcher's role biasing the research or the process of implementation. Most of the respondents thought that the researcher would not have had much influence on the process. Reasons given were that the guideline implementation was a team effort; that because the researcher only worked part time as a clinician, many staff did not realise there was a dual role; that the researcher was not very involved because it was the project group leading the change; and that there had been no observed impact on the way people were thinking about the practice area of the guideline. One respondent thought that the study itself would not have a big effect on what people were doing. One respondent was not sure whether the dual role would contaminate the research and another thought potential bias would be overcome by gathering lots of people's views. Two respondents specifically thought that the strong personalities of people involved with the project meant they were not easily influenced.

9.6.2 Completion of the Project

Possibly the most influence the dual role may have had, was by increasing the interest in the area of practice covered by the guideline, according to two respondents. One of these respondents thought that being part of a research project had helped the guideline go through the process of implementation more completely than might otherwise have happened.

9.6.3 Skills and Resources

Four respondents commented that the researcher's skills were seen as a resource to the research site, and one of these felt that these skills were a specific resource to the project. Two respondents felt that being a clinician brought credibility to the research and one thought that the credibility of the clinician as a researcher was now more accepted. One respondent thought that the managers had been challenged by the researcher's knowledge.

9.7 PRESENTING A BALANCED PERSPECTIVE

The theme *presenting a balanced perspective* emerged from the reflective diary data. There were several diary entries demonstrating that the researcher was keen not to be seen as favouring one practice of extubation over another.

[Following a discussion with colleagues about the different practices for extubation I realised that] *I decided to add that patients in theatre are recovered using a face mask over an [endotracheal] tube and are quickly extubated. I didn't want to seem that I sided with the either practice so added something about reducing the pressure support to minimum quickly when recovering our patients because they mostly didn't need long slow weaning because of good pre-op lung function and that it wasn't only the size of the breath that ensured they had adequate gaseous exchange.*

These entries occurred particularly during the period when there was discussion at the research site about which of the two extubation methods should be recommended in the guideline. The four categories of this theme are identifying my own views of practice and implementation, avoiding giving my opinion, challenging perceptions of my views of practice and researcher/clinician role conflict.

9.7.1 Identifying My Own Views of Practice and Implementation

Thinking about presenting a balanced view to colleagues helped the researcher think and articulate the things about her own practice that she saw as important. In this case using the practice that best suited the patient's response.

...I suppose I'm developing a way to articulate my views and its making me think that its not the method you extubate that should be the key guide, but how the patient responds, with the aim of extubating as soon as is safely as possible.

Before the project, the researcher was aware she preferred using the pressure support mode on the ventilator because of her previous experience of weaning patients from artificial ventilation in general intensive care units. However, discussing the advantages and disadvantages of the two different options and seeing both work, meant that the researcher became more confident in using the minimum pressure support as soon as the patient woke up and started breathing for themselves and increasing the pressure support only if they were not able to manage to ventilate themselves adequately. This category is closely linked to the second theme, *implicit knowledge*, which will be discussed further in section 9.8, although this category differs because it concerned the development of the researcher's awareness of her own practice.

Various reflections in the diary also demonstrated the researcher's growing awareness that not everyone used ASB [pressure support] in the same way and this accounted for some of the frustration of the nurses who favoured the face mask option had with ASB.

A discussion with a colleague about patients were being left unnecessarily long on ventilators prompted the following reflection.

It made me think that what was more important was finding the minimum level of pressure support the patient needed as soon as they woke up rather than assuming all patients needed a fairly high level of support and weaning them down slowly. I could see her frustration, but felt that concluding that ASB was not good and every one should be assessed using a the face mask and assessing breathing using a bag was not the only answer to improving practice. Increasing people's awareness of using ASB to recover patients rather than wean them slowly is an alternative option. Its about being clear what we are trying to achieve and why, rather than how.

9.7.2 Avoiding Giving My Opinion

Another strategy the researcher used to give a balanced view was to avoid giving her opinion if it would seem that she favoured the pressure support method of extubation. Sometimes this involved the researcher saying that both practices had their merits and at other times she avoided joining in conversations about extubation. One entry also shows that the researcher decided to referred people to other members of the project team rather than being drawn into a discussion.

As I actually don't know where this discussion has got to re face mask vs. ASB [pressure support] I think it will work to refer questions to other members of the project team. This might also help not ending up in heated discussions defending ASB [pressure support] with people who think ASB is taking over. Any way all I could do is represent their view to the team, so its probably best they do it themselves.

9.7.3 Challenging Perceptions of My Views of Practice

The researcher was aware that my practice preference was usually using pressure support ventilation whilst assessing patients for extubation. The researcher felt that most staff would therefore assume she thought this practice was best because they could see that is how she practiced. Other reasons to support this assumption were that the researcher's nursing background was in intensive care and that she was, therefore, more familiar practicing with ventilator weaning modes. On a few occasions the diary reflections showed that the researcher consciously thought about how to challenge the assumptions she thought other nurses had about her views.

I was helping the nurse with her patient in the next bed to my patient, when [name] asked me if she could help do anything for my patient like put them on a face mask. I said they were already on minimum pressure support and I asked [name] to check a blood gas for me and extubate if it was OK. I new she'd seen the patient waking up recently and I hoped their gases would be OK, so I could show her that using ASB [pressure support] could be as quick as the face mask option [name preferred using the face mask method to extubate her patients]. The patient was able to be extubated. I felt that I had challenged the assumption that I would "wean" a patient because I was using ASB [pressure support], rather than assess them for extubation first.

On another occasion the researcher noted that:

The patient had recently woken up and I'd just tried them on ASB [pressure support], but it seemed to irritate them. So I had used the face mask option and the patient seemed much calmer and was doing well. I asked [name] to help extubate. She said she thought I preferred using ASB [pressure support]. I remember thinking this is a chance to show her that I'm not opposed to the face mask. I said I did usually, but some patients were more comfortable with the face mask and so I would always use it if it suited the patient better. I feel pleased that I had the chance to show I wasn't against the face mask option.

9.7.4 Researcher/Clinician Role Conflict

During the development and implementation process, there were two occasions where what the researcher had read for her research caused her a dilemma regarding influencing the process of guideline development and implementation versus wanting the process to be the best possible for patient care. On one occasion the project team specifically asked the researcher about her literature review. Fortunately their own conclusions from what they had read were similar to the researcher's views of the literature. In this case the researcher reflected that her research knowledge would not make a difference to the project development.

On the second occasion, the researcher had come across a resource that would facilitate an audit of practice, with tips about changing practice. Her dilemma was whether she should mention the resource and, if so, how strongly to should present it. The resource could have influenced the way the project was implemented and therefore affected her research's validity. On the other hand the resource also might have been used to improve patient care

which the researcher considered part of her role as a clinician. The researcher decided on a compromise. She decided to bring the resource to the teams attention, by asking if they were aware of it and suggesting it might be worth looking at, but she would leave it to the implementation team to decide whether to follow it up. The researcher felt this was reasonable, as in her clinical role she was not involved in the decision making during the implementation process, so it was appropriate to leave the decision to those that were.

No other diary entries indicated that the researcher felt other areas of role conflict and the data from the participant interviews did not raise it as an issue from their perspectives (see section 9.6).

9.8 IMPLICIT KNOWLEDGE OF THE SETTING

The second theme that emerged from the reflective diary was *implicit knowledge of the setting*. This knowledge was the knowledge the researcher had about the research site from her clinical role. This implicit knowledge became conscious through reflections on how, what the researcher already knew, affected the research. Two categories emerged; effects on the research design and understanding my implicit knowledge.

9.8.1 Effects on the Research Design

The category, effects on the research design, had two sub categories, identification of the research idea and knowing who to interview.

9.8.1a Identification of the research idea

The idea of researching how nurses made their decisions to extubate patients emerged from the researcher's reflections on her practice and experience at the research site before the study commenced. The idea to evaluate the impact of the clinical guideline for extubation

resulted from the research site's decision to review practice, including developing a guideline, and the researcher's interest in service evaluation research. In the reflective diary, used once the project had started, the researcher's thoughts on the development of the ideas were linked to reading about how research ideas and questions are often developed in ethnographic studies. The reflections were a result of the tension between developing a clear project and research question for the whole evaluation study and using a mixture of methods, drawing from both positivist and naturalistic traditions.

My research question/topic is really influenced by wanting to look at the impact of the guideline on patient outcomes using the ITS [interrupted time series]. But exploring the results and reasons for the results is really important too. Is there an inconsistency then? The topic hasn't emerged from the interviews like it might in ethnography, but it has from my experience before this study. That's not so different with lots of research- I'm sure lots of questions arise from what people know already and what they've read. So the research question is not developed as part of an ethnography. This then is a difference between my study and ethnography. The question comes from the evaluation side rather than developing it from interviews etc during the study.

9.8.1b Knowing who to interview

Reflecting on the differences between practitioner and outsider researcher traditions in ethnography, the researcher realised that the people she chose to interview for the study came from her implicit understanding of the research site. The researcher realised that she had not had to learn how to access key informants for the research, as an outsider would. This was because she already knew which staff and managers had been involved in the extubation guideline project and she worked with all the staff who used the guideline. This

ease of access could be considered one advantage of being a practitioner researcher (see discussion in chapter 6, section 6.4.2).

9.8.2 Understanding My Implicit Knowledge

This category was linked to development in the researcher's thinking about what her implicit knowledge actually was as an insider at the research site. Some of the reflections were about the researcher's own assumptions and some about shared cultural assumptions.

Interviewing [name] when they talked about characters being strong and therefore my influence would probably be minimal, made me think I knew what they meant because I know the people [name] was referring to and [name] knew I knew. Would [name] have said that to someone else? Should I have pursued that topic a bit more and not relied on my assumption of shared understanding?

Most reflections were entered during the analysis and writing up stages of the project, when the researcher was wondering how much her own perspectives influenced the interpretation of the data. The focus of most of these reflections was the learning culture category of the *context theme* (section 9.2.3). For example:

The theme of learning seems to be prominent in the analysis. Is this because learning is important to me or because that culture really exists [at the research site]? One of the positives about working there, though, is that people do seem to share that value with me. It's hard to tell for sure that the prominence it's got is because it's a feature I warm to, but it is interesting that in the interviews, people often talked about the guideline in the context of learning/teaching and its those words that have emerged in the indexing of the [interview] transcripts...

Another area of reflection concerned the *tensions* theme. Having lived through the development and implementation of the guideline, the researcher had experienced some tensions and wondered if her internal feelings of tension, and in many instances resolutions, influenced the choice of word for this theme.

The researcher felt she was more aware of and identified with the project team's perspective and frustrations during the implementation rather than the managers' perspective. In this instance her implicit knowledge came from being part of the project team. It was also framed in a staff nurse role perspective. The researcher decided to consciously be careful to use the data from both managers and the project team in the formation of in the category managers/other staff in the *tensions* theme (see section 9.4.5). The researcher tried to interpret and present what the data actually said by being conscious of her feelings about any issues that were raised and attempting not to convey these feelings. Having primary data from both staff and managers helped this process. It was also helped by a decision made on reflection to view comments as perspectives from people shaped by their different role responsibilities. The reader can judge whether this attempt seems credible when reading section 9.4.5.

9.9 SUMMARY

Three key themes were identified in the analysis of the respondents' data concerning the guideline development and implementation. These were: the *context*, the *process* and *tensions*. Each theme had a number of categories and sub-categories all of which could exert some influence on the implementation of the guideline. This highlights the complexity of the process involved in implementing this guideline. The impact of the researcher on the project was also explored in the analysis of the reflective diary and

respondents' data on this topic. Three themes emerged, *areas of potential influence, presenting a balanced perspective and implicit knowledge of the setting.*

The context in which the implementation was taking place seemed to have shown two main transitions in progress at the research site. Firstly the skill mix, and to some extent the case mix, changes and resulting cultural changes in the attitudes to extubation and the experience of staff caring for cardiac surgical patients. Secondly there seemed to be a cultural change in the way changes were implemented, from a top down approach to a more bottom up approach. These two contextual and cultural changes were ongoing, so hence the use of the term transition. They also give some insight into changing contexts in which nurses can be working when they introduce practice developments.

Learning appeared to be a core value in the culture of the research site. Learning was discussed in many ways, from learning through the process of implementing the guideline, to the guideline's main value becoming a teaching and learning tool.

The *process* theme encompassed both planned aspects of the development and implementation of the guideline and adaptations the project team had to make along the way and so may be considered an emergent process. The implementation did not follow a straightforward and orderly process. Dealing with people's reactions and concerns seemed to take a lot of time and was integral to the resulting product (i.e. the guideline). It also led to dissatisfaction with the formal procedures for approving and reviewing such developments. As a result a new forum was set up to improve these aspects of any developments related to clinical governance, such as clinical guidelines. This could also be considered another evolution resulting from the changing culture for implementing changes at the research site.

The product appeared to be a consensus of experience, opinion and some research evidence. However, the lack of high quality research evidence for the best method of assessing a cardiac surgical patient's readiness for extubation seemed to have resulted in compromise and different practice preferences being incorporated. As a result, it seemed that none of the experienced nurses who were interviewed had had to change their practice.

The tensions created by different practice preferences, gaps in high level research evidence and individual's resistance to change were very real issues in this project. The resulting discussions delayed the implementation considerably. In some ways this demonstrates the difficulties of using research in practice. Presenting research to clinicians does not automatically result in them changing their practice. All those involved accepted that early extubation was safe based both on their experience and evidence from clinical trials. However, there was a lack of high level research evidence of best practice on how to extubate, which was the substance of this guideline. The result was considerable conflict and discussion about parts of the practice that had little research evidence from clinical trials, (i.e. the choice of method for supporting breathing whilst assessing the patient's readiness for extubation, and exact cut off points for the various assessments, beyond which it is unsafe to extubate patients). One difficulty was that individuals used various types of evidence to argue their case, from experience to citing research papers where their preferred method had probably been used. It appeared that individuals did not always seem to be able to value similar or stronger evidence for a different point of view. As one respondent commented, this is probably more to do with personality than evidence. The final guideline was described either as a compromise or representing a consensus view. Some respondents even had concerns that the compromises had resulted in a document of individual views rather than one based on sound empirical evidence.

Throughout the process of implementing the guideline, *tensions* were evident and this was the third theme to emerge from the data. Although working with, working through or resolving the tensions that the process had highlighted appeared to take considerable time and energy, they could be considered a creative force in the process. Dealing with each of the tensions allowed the guideline to meet varying needs, stimulated debate and discussion, not only about the practice of extubation, but also broader issues such as managing resistance to change, differences in outlook and the needs of managers and staff.

It is difficult to be sure of the impact the researcher had on the implementation of the guideline because, although respondents did not appear to mind giving their views on this subject, it is possible that they may not have felt comfortable telling the researcher what they really thought. It is also equally possible that respondents were more comfortable talking to the researcher than an outsider because they knew her and several mentioned positive aspects of a clinician conducting research. The researcher's reflective diary also gave another perspective of her role and impact on the research. Taking a subtle realist approach (see chapter 6, section 6.3 for further discussion) the different perspectives are valid and may point to a more objective truth when taken together. Three themes emerged from these two data sources, *areas of potential influence, presenting a balanced perspective and implicit knowledge of the setting*.

There were three areas identified by respondents where there may have been an influence on the guideline implementation. Firstly, the risk of bias in the guideline development and implementation was not thought to be significant by the respondents. Secondly and perhaps most significantly was the increased interest in the guideline development and implementation project because of the research. This may have influenced the project

completion. The implication of this is that without an external motivator like a research project, practice developments, such as guidelines, may encounter difficulties that result in incomplete or failed implementation. This view was expressed by only one respondent and may therefore not represent a true picture. Its significance is difficult to assess without further investigation. The third area of influence was the skills and resources the researcher brought to the research site. In particular the researcher's clinical skills brought credibility to the research. This may have influenced the willingness of staff to be interviewed and the quality of the data, although no respondent mentioned any specific impact of this credibility.

Although *presenting a balanced perspective* was important to the researcher, none of the respondents mentioned that her views of practice had impacted on the guideline development or implementation. This could be seen as a positive outcome, in that the researcher's views were not seen as an issue. With the exception of the possible influence of the research on the completion of implementation process, it seems that the researcher did not exert any obvious influence on the content of the guideline and how it was implemented. This means that the researcher has confidence that the outcomes in the interrupted time series part of the research should not be unduly biased by the researcher's own views.

The researcher's awareness of the impact of her *implicit knowledge of the research site* seemed to develop over the course of the study. Particular instances in interviews, issues read in literature on ethnography or challenges arising from data interpretation resulted in reflections raising the researcher's awareness of this implicit knowledge. The influence of the implicit knowledge was clearest in the development of the research idea and question and in accessing respondents. Rapport with respondents may have meant that shared

culture gave access to some views that an outsider may not have been given, but it may also have precluded further exploration of some issues because of assumption of a shared understanding.

The themes on the researcher's role and impact on the study may help readers to assess the credibility of the themes *context, process and tensions* and give some insight into the issues respondents and the researcher felt were important concerning the impact of the researcher on the project. This potential impact is discussed further in chapter twelve.

CHAPTER TEN

SYSTEMATIC REVIEW DISCUSSION

The systematic review demonstrated some of the advantages of early extubation. Intensive care unit (ICU) and hospital length of stay can be shortened as a result of extubating adult patients early after cardiac surgery and the implications of this are discussed below. There were also some limitations, particularly associated with the quality of the studies reviewed. The results of the systematic review are less conclusive about the impact of early extubation on morbidity and mortality and practice may have changed since the studies included in the review were conducted.

10.1 MORTALITY AND MORBIDITY

The design of all six studies that met the inclusion criteria for this systematic review failed to address important outcomes for patients. In particular, no attempt was made to calculate the sample sizes required to determine whether the rates of mortality and important morbidities after cardiac surgery are changed by the time chosen to extubate. No trial was designed to determine whether these rates in the early and conventional extubation groups are equivalent, therefore the absence of a statistical difference in the important outcomes examined by this review cannot be interpreted as representing evidence of no effect.

10.2 INTENSIVE CARE UNIT AND HOSPITAL LENGTH OF STAY

10.2.1 Implications for Resource Use

The strongest evidence, in this systematic review, about the benefits of early extubation were shorter intensive care unit (ICU) and hospital stays, a reduction of seven hours and one day respectively. The finding for shorter hospital stay, however, is based only on two of the six included studies with a total of 132 patients. The implications of the reductions in resource use (shorter ICU and hospital length of stay) are cost savings and increasing the number of cardiac surgical operations that can be performed (see section 10.2.3 for further discussion of the latter).

Shorter ICU stays have implications for costs of care, but the fact that a patient is ready for discharge from ICU does not necessarily mean they can be transferred to a lower dependency area immediately. There would need to be a bed available and this is affected by many other factors, for example the level of care needed by patients in other areas of the hospital can have a knock on effect on bed availability. Straka et al., (2002) reports that their local regulations (in the Czech Republic) for reimbursement require a minimum ICU and hospital stay to register a fee for coronary bypass graft surgery which impacts on both ICU and hospital length of stays.

Only Cheng et al's study (1996a) gave results of ICU length of stay for when patients met clinical criteria indicating they no longer needed intensive care and for when they actually left ICU. Other studies did not specify whether discharge from ICU was or was not based purely on clinical readiness. Silbert et al. (1998) stated that their practice was that all patients stayed in ICU until the day after surgery as routine, commenting on the need for

reorganizing the service to accommodate patients who do not need such long periods in ICU. Quasha et al. (1980) stated that the lack of difference in ICU length of stay in his study was affected by ICU bed availability, surgical load and the willingness of clinicians to transfer patients to the ward. Some studies have investigated whether such patients could be cared for in less expensive alternative units (Chong et al., 1992, Chong et al., 1993 and Massey and Meggit, 1994). These studies demonstrated successful outcomes caring for patients in cardiac surgical recovery areas rather than in ICUs.

10.2.2 Impact of Shorter Stays on the Risk of Complications

A shorter stay in ICU is likely to reduce the risk of infection for patients, but how much difference seven hours makes is debatable because most cardiac surgery patients, whether they are extubated early or not do not stay much more than 24 hours in ICU. Studies have tended to look at ICU stays of more than 24 hours and the risk of infection is reported as greater after a stay of 48 hours (Vincent et al., 1995) or 4 days (for ventilator acquired respiratory tract infections) (Bouza et al., 2003). The risk of acquiring infections is associated with invasive lines and procedures such as endotracheal tubes, central venous lines, intra-aortic balloon pumps and urinary catheters (Kollef, 1993, Vincent et al., 1995, Robello et al., 1996 and Bouza et al., 2003). Recovering patients and removing invasive lines and tubes as quickly as their condition allows is important for reducing the risk of infection.

The removal of invasive lines and tubes also makes early mobilization easier. Mobilizing early helps reduce complications of surgery. Mobilizing is often practically easier for patients in a lower dependency ward area compared with an ICU. Wards are also generally

considered to be less stressful environments for patients and carers compared to an ICU (Scott, 2004).

10.2.3 Effects of Shorter Stays on Operation Numbers

The most likely effect of reducing ICU stay is to increase the number of operations performed, but this requires organizational facilitation of optimal bed use in the cardiac surgery departments, from planning of surgical lists, to facilitating early discharge from cardiac wards and ensuring payment for the episode of care is appropriate.

10.3 LIMITATIONS OF THE FINDINGS

10.3.1 Limitations of the Study Populations

The findings of this review are limited to only a part of the cardiac surgical population. The studies included only elective patients (except Reyes et al., 1997) mainly under the age of 70 to 75, who were not considered high risk. Some studies have looked at whether early extubation is suitable for high risk patients (see chapter two, section 2.3). Findings vary but it seems that preoperative risk factors, such as age or poor left ventricular function should not preclude these patients from fast track protocols (Cheng et al., 1997, Ott et al., 1997, Lee et al., 1998, Rady et al., 1998, Rady and Ryan, 1999, Wong et al., 1999, Walthall et al., 2001, Simeone et al., 2002 and Alhan et al., 2003).

10.3.2 The Role of Perioperative Factors

Perioperative factors, such as length of time on cardiopulmonary bypass, red blood cell transfusion and the need for an intra-aortic balloon pump are shown in some studies to influence how long a patient needs to be ventilated. (Cheng et al., 1997, Rady and Ryan, 1999, Wong et al., 1999 and Walthall and Ray, 2002). Authors do not agree exactly which intraoperative variables influence outcomes (see chapter two, section 2.3, for further details). Most of these studies are observational studies that use various anaesthetic techniques, weaning protocols, extubation criteria and postoperative analgesia regimens all of which make comparisons difficult and make conclusions tentative.

10.3.3 Changing Practice

Another limitation of this systematic review is that the most recent of the included studies was published in 1998, using data from the mid 1990s. Practices and participants may not be representative of cardiac surgery today. Since then there has been an increasing number of operations performed off cardiopulmonary bypass (off-pump). The length of cardiopulmonary bypass during surgery may contribute to longer ventilation times (Rady and Ryan, 1999 and Walthall and Ray, 2002) and so off-pump surgery may be beneficial to patients. However, Cimen et al., (2003), in a small trial of 36 patients, found there were no significant differences in respiratory outcomes, lung function and extubation times between on-pump and off-pump patients.

Anaesthetic techniques used in fast track protocols have changed since the mid 1990s and have been the subject of several randomised controlled trials. Alternative drugs to fentanyl for general anaesthesia such as remifentanyl and sufentanyl have been studied (Myles et al.,

2002). Pancuronium has been compared with rocuronium for neuromuscular blockade (paralysing agents used during surgery) (Murphy et al., 2003 and Thomas et al., 2003). Both studies suggest that patients given rocuronium recovered neuromuscular function significantly faster. Some studies have compared general anaesthesia with combined epidural and general anaesthesia. Royse (Royse et al., 2003) looked at high thoracic epidural combined with general anaesthesia and found a reduction in extubation times, and better pain control in the postoperative period. Bettex et al. (2002) found a reduction in extubation times and pain for patients receiving a lumbar intrathecal dose of sufentanil and morphine compared with patients receiving a continuous intravenous infusion of sufentanil.

It was not possible to perform a subgroup analysis to compare the outcomes for patients extubated within four hours of surgery compared with those extubated later. However, there is a growing literature on the safety and efficacy of immediate extubation or very early extubation (within one hour of surgery). Studies again use a variety of anaesthetic techniques to achieve this (Royse et al., 1999, McGuire et al., 2000, Montes et al., 2000, Royse et al., 2002, Nicholson et al., 2002, Straka et al., 2002 and Canto-Pastor et al., 2003). Two studies found it possible and safe to immediately extubate between 75% (Canto-Pastor et al., 2003) and 94% (Straka et al., 2002). Montes et al., (2000) question the value of immediate extubation that does not reduce ICU or hospital length of stay, unless the service can be organised to deliver care more flexibly. They safely extubated 50% of patients in the operating theatre, using a general rather than a general combined with epidural anaesthetic. They found that immediate extubation did not reduce ICU or hospital length of stay.

The evidence from the majority of the studies in this discussion section should be treated with caution because some are observational studies and many of the randomised controlled trials may be underpowered. Their results may therefore not give a true picture of the effects of the interventions discussed.

10.4 SUMMARY

The systematic review produced evidence that early extubation can shorten ICU and hospital length of stay. This may reduce resource use, but organisational factors such as bed availability can also play a part in this. The majority of the studies were conducted in the 1990s, when there was an increasing drive for cost effective health care and the associated need to demonstrate resource reductions healthcare organisations. Patients may also be interested in the possibility of shorter hospital stays and an increase in the number of operations performed. However the evidence relating to the variables for mortality and morbidity, of key interest to patients as well as clinicians, was not clear. There was no demonstration of the use of power calculations for determining sample sizes that would be sufficient to accurately estimate the risks of early extubation on these outcomes when compared with conventional extubation.

Changing practice means that the findings comparing early and conventional extubation are not as current as interest in determining how early extubation can be performed safely. This systematic review was not able to contribute to this discussion due to a lack of data from the included studies on the proportion of patients extubated at different times within the early extubation samples (i.e. it was not possible to perform the intended subgroup analysis).

CHAPTER ELEVEN

INTERRUPTED TIME SERIES STUDY DISCUSSION

11.1 INTRODUCTION TO DISCUSSION

How evidence, including clinical guidelines, affects patient outcomes is acknowledged as an under researched element by researchers from many different professional backgrounds and with differing approaches to research (Kitson et al., 1996, Bero et al., 1998, National Health Service Centre for Reviews and Dissemination, 1999 and Grimshaw et al., 2004). The effects of clinical guidelines on patient outcomes, seems a crucial element in discussion about their usefulness. This study sought to contribute to the discussion through using an interrupted time series analysis to test the effects of a clinical guideline for early extubation on patient outcomes.

In the early 1990s, Grimshaw and Russell (1993), from the evidence in their systematic review, suggested that well developed and effectively implemented medical guidelines may improve patient outcomes. The lack of evidence for the best implementation strategies is one reason for the difficulty in demonstrating the effects of clinical guideline on patient outcomes. Several subsequent systematic reviews (Grimshaw et al., 1995, Oxman et al., 1995, Bero et al., 1998, National Health Service Centre for Reviews and Dissemination, 1999 and Grimshaw et al., 2004) have investigated the effectiveness of strategies to implement research in practice. The poor quality of primary research makes it difficult for the reviewers to draw firm conclusions about the effectiveness of the strategies and the effect on patient outcomes. Thomas et al. (1999a, 1999b and 1999c) could not demonstrate a link, similar to that of Grimshaw (1993), in the nursing literature due to the poor quality of the research.

The evidence for the effectiveness of nursing interventions on patient outcomes is also a relatively new area of investigation. Understanding of how nurses' roles affect patient outcomes is growing (Lee, J L et al., 1999, Irvine et al., 1998b and Doran et al., 2002). A systematic literature review demonstrated that there is some evidence to link the quality of nursing care with patient outcomes both in hospital and after discharge (Lee, J L et al., 1999). This highlights the importance of delivering high quality care. Rigorous evidence based guidelines that are successfully implemented may contribute to high quality care. Successful implementation seems more likely in an environment that is using quality improvement strategies to promote change (Halladay and Bero, 2000).

11.2 DEVELOPMENT OF RESEARCH METHODS FOR EVALUATING CLINICAL GUIDELINES

One reason for the lack of research into the effects of clinical guidelines on patient outcomes is that there is paucity of research into methods that capture the complexity of the use and effects of guidelines. Guidelines are implemented over long time periods and the effects on patients often depend on factors such as compliance with recommended treatment also over time (Marshall et al., 2000). This means randomised controlled trials (RCTs) may not be able to capture the whole of this complexity. Studies that measure outcomes and only one or two specific time points may also not capture the whole picture. Before and after observational studies may show changes in outcomes but are not considered as rigorous as RCTs because of difficulties in controlling confounding variables. Studies that use statistical modelling of observational data may provide a way of capturing the complexity of guideline implementation and allow outcome variables to be investigated over time.

Interrupted time series offers one such type of statistical modelling. Marshall et al. (2000) were able to show how statistical modelling may prove useful in clinical guidelines research. Although, they used a different type of model (Cox's proportional hazards time-varying covariate model) rather than interrupted times series, they compared it to a statistical analysis that did not vary with time. Marshall et al. (2000) were able to illustrate how models that capture time may be useful in clinical guidelines research.

Marshall et al. (2000) investigated adherence, over time, to treatments recommended in guidelines for human immunodeficiency virus (HIV) patients. They used the HIV guidelines because they were based on high quality evidence, which is considered to contribute to validity of guidelines (see discussion in chapter twelve, section 12.3.1). Marshall et al. (2000) wanted to find suitable statistical models that capture differences in when outcome events happen over the study period. They also wanted models that take into account the differences between patients at the beginning of the study (baseline) and that can model adherence to the guideline (measured by looking at the physicians' prescribing records) over time. They compared and contrasted findings with a simple logistic regression model, the Cox proportional hazards model and a time varying model (Cox's proportional hazards time-varying covariate model). The time varying model produced more reliable results. The authors considered it better because it modelled outcomes (death or progression to acquired immunodeficiency disease (AIDS)) that could occur at different times over the study period, and it also enabled them to consider a minimum period of exposure to the treatment (adherence to the guideline for at least 10% of the study period). They recommend validation of the model in further research.

Studies that use statistical models, therefore, may provide a way of improving the quality of research into implementing clinical guidelines. They can take into account changes that

occur over time and provide more rigorous evaluations than before and after observational studies. The interrupted time series part of this study aimed to do this. It was chosen because it was a suitable model to look at repeated measures of particular outcomes over time following one particular intervention (early extubation) rather than the progress of individual patients following a particular course of treatment. It differed from the Marshall et al. (2000) study in this respect.

11.3 DISCUSSION OF THE RESULTS

The interrupted time series analysis demonstrated that the early extubation guideline had no effect on any of the outcome measures; extubation time, time to self-ventilating on 40% oxygen, intensive care (ICU) length of stay and hospital length of stay (see chapter eight, section 8.3). No trends were identified in the within person control variables, which demonstrates that the results for the outcome measures were unlikely to have been affected by confounding variables that differed over time. The reasons why there was no effect on the outcome measures are discussed below.

It is possible that the outcome measures chosen were not associated with early extubation and are invalid. The literature review (chapter two, sections 2.2.2a and 2.2.2b) and the results and discussion of the systematic review (chapter seven, section 7.1.3 and chapter ten) show that extubation time, ICU length of stay (or a patient's readiness for transfer to a high dependency unit (HDU)) and hospital length of stay are affected by early extubation. Time to self-ventilating on 40% oxygen was not used as an outcome measure in any studies reviewed and may not be a clinically significant outcome. However, it was selected because it demonstrated the patient's progress to recovering full respiratory function following extubation. The outcome, time to self-ventilating on 40% oxygen, may be of clinical interest, as the other respiratory outcomes (reintubation and need for continuous

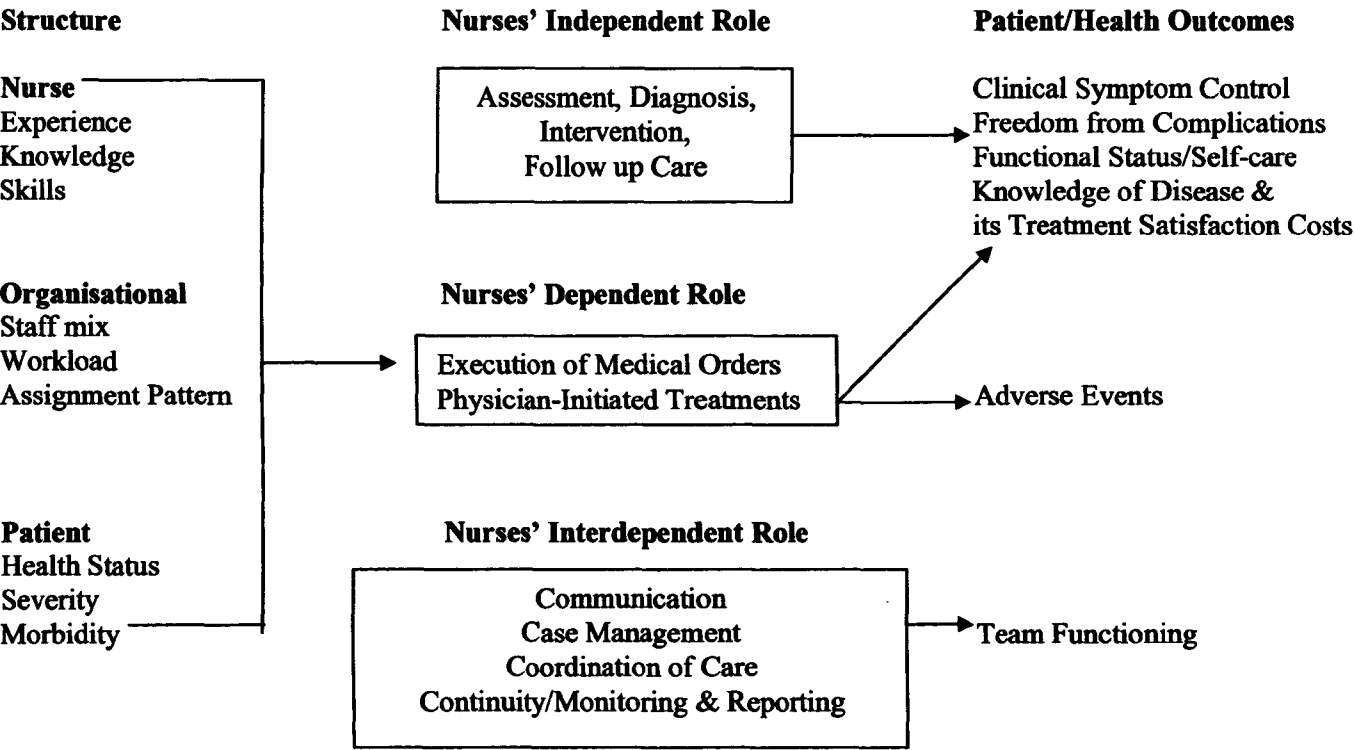
positive airway pressure (CPAP)) selected to detect increases or decreases in respiratory complications had low incidence rates and there was insufficient data for a time series analysis.

Although there was a low incidence of reintubation rates and rates of needing CPAP, the rates for the two years samples of the study were not statistically significantly different. The reintubation rates for this study, 3% for year one and 6% for year two compare with other studies that have reported rates between 0% (Klineberg et al., 1977, Foster et al., 1984, Higgins, 1995, Marquez et al., 1995, Michalopoulos et al., 1998 and Silbert et al., 1998) and 4% (Prakash et al., 1977). The reintubation rate within 24 hours of surgery was 1.6% in the meta-analysis for the systematic review (see graph 7.1.3a, in chapter seven). Although the reintubation rate in year 2 of the study was 6% and therefore higher than the 4% reported in other studies, there was no statistical significance between the rates of 3% and 6% in years one and two of the current study. This indicates that the reintubation rates were similar to those reported in the literature.

Research into nursing outcomes by Irvine et al (Irvine et al., 1998a, Irvine et al., 1998b, Sidani and Irvine, 1999 and Doran et al., 2003) has developed and tested the Nursing Role Effectiveness Model (Figure 11.2). It shows what parts of the nurse's role have been shown to impact on particular patient outcomes and may therefore be considered as another way to investigate the validity of the outcomes chosen for the interrupted time series in the current study.

The Nursing Role Effectiveness model (Irvine et al., 1998a) uses a structure, process outcome framework (Donabedian, 1980). Donabedian's work has been influential in identifying what influences the quality of patient care in healthcare organisations and

Figure 11.2 The Nursing Role Effectiveness Model (Irvine et al., 1998a)



attempts to reflect the complexity of what a nurse does. The role of the nurse is the process part of the model (Figure 11.2). This is conceptualised in three distinctive parts, independent, dependent and interdependent. The structural parts model the influence on the role of the nurse, which impacts on the patient outcomes. How effective a nurse can be not only depends on the structural aspects she has to work with, but also the quality of functioning in each of her roles. The effectiveness of the nurse's role can be measured by the patient/health outcomes.

The clinical guideline for early extubation was a nurse-led intervention and could be regarded as being part of the nurse's independent role in the Nursing Role Effectiveness Model (Irvine et al., 1998a). According to this model the types of outcome affected by the nurse's independent role include freedom from complications and functional status/self care. Early extubation is about helping the patient back to independent ventilation (a functional status) and it is about avoiding complications that could be caused by poor decision making concerning when to extubate the patient. Time to extubation and time to self-ventilating on 40% oxygen are measures of functional status, as they show the patients' progress to independent breathing. Readiness for transfer to a high dependency unit (HDU) and hospital length of stay may also be regarded as measures of functional status in the sense they show the patient's progress from dependence to independence following cardiac surgery. The hospital length of stay is not always a reliable outcome measure of a patient's functional status because hospital length of stay can be affected by other factors such as transfer to another hospital or problems in arranging transport home. Applying Irvine et al's model (Irvine et al., 1998a) to the outcomes in this way could be argued to support the validity of the outcomes selected for the interrupted time series analysis because the part of the nurse's role (independent role) has been linked to patient outcomes related to functional status.

11.4 LIMITATIONS OF THE INTERRUPTED TIME SERIES

STATISTICAL MODELS

Another reason that the outcome measures were not affected by the early extubation guideline could be that the statistical models used in the interrupted time series analysis were not sensitive enough to detect any differences. A longer pre-intervention time series of at least two years would improve the length of forecasts and allow more sophisticated modelling such as ARMA or ARIMA (see chapter five for details of the interrupted time series methodology). This is a limitation of this study. However, the exponential models that were used were able to smooth the data and to predict three months' values into the second year. The trends from both years in all outcomes were reasonably constant, showing no great upward or downward trends. The results for the whole of year two, in particular do not show very different trends compared with the three month forecast based on the first year's data. The comparison of the forecast with the actual second year data, therefore, provides some insight into the longer term trends in the second year. The exponential models would also have modelled any significant changes in year two had the outcomes been affected by the intervention. The use of the models in the interrupted time series analysis appears valid.

The validity of the time series analysis is further strengthened by the within person controls (colloid fluid balance and number of arterial blood gas samples). The within person controls data values were constant between the two years as was expected. One reason is that the early extubation guideline should not have affected these outcomes and appears not to have done so. The other reason is that all the data related to the nurses' decision making processes collected before and after the intervention were unlikely to have been affected by confounding variables that differed over time.

11.5 INSIGHTS FROM THE QUALITATIVE DATA ANALYSIS

The qualitative part of this study aimed to provide insights into the results of the time series analysis. Taking into consideration the results of the qualitative analysis, it appeared that the early extubation guideline allowed experienced nurses to continue to practice as they had before its implementation (see chapter nine, section 9.3.6a). Inexperienced nurses were also able to learn the existing practices by using the guideline (chapter nine, section 9.2.3). In other words the early extubation guideline did not appear to change practice. This finding appears to provide a good explanation for why there were no significant changes in the outcome measures in the interrupted time series analysis.

11.6 SUMMARY

There is a paucity of research using methods that can capture the complexity of guideline implementation and demonstrate their effects on patient outcomes. Statistical modelling that can capture changes that occur over time in the health care environments where guidelines are introduced may be a way forward. Interrupted time series is one such method.

Although the results of the interrupted time series analysis demonstrated that the early extubation guideline had no effect on the outcomes, this seems to be a reliable and valid finding. The qualitative data analysis seems to provide the most likely reason for the results. It appears that the clinical guideline did not result in a change in clinical practice and so it did not affect the outcome measures.

The reasons why practice did not significantly change emerged from the qualitative data and are discussed in chapter twelve. Although the interrupted time series and the

qualitative parts of this study were not designed to test the effectiveness of the development and implementation strategies used by the clinicians at the research site, the qualitative analysis may provide some interesting insights into these processes. The literature on guideline development and implementation is compared and contrasted with the results of the qualitative analysis in the following chapter.

CHAPTER TWELVE

DISCUSSION OF QUALITATIVE DATA ANALYSIS

12.1 INTRODUCTION

The aim of the qualitative part of this study was to explore reasons for the results of the interrupted time series analysis and to identify factors influencing the successful implementation of a clinical guideline. The qualitative interviews and resulting data focused on the process of development and implementation of the clinical guideline. The three derived themes of the *context*, the *process* and *tensions* reflect this focus. The contribution of each of the themes to explaining why the guideline did not appear to change practice is explored below. The researcher's reflective diary and data from the interviews exploring the impact of the researcher on the guideline project and the research produced three themes, *areas of potential influence*, *presenting a balanced perspective* and *implicit knowledge of the setting*. These themes are related to the discussion of the *context*, *process* and *tensions* themes where they may impact on the discussion. The category, effects on the research design from the theme, *implicit knowledge of the setting*, is not discussed here as its relevance is related to the research design discussed in chapter 6, rather than the themes *context*, *process* and *tensions*.

In this chapter, the themes *context*, *process* and *tensions* are discussed and compared with the literature on clinical guidelines. Clinical guidelines are one method of introducing evidence in practice and the literature on the implementation of evidence in clinical practice is also considered. The influence of the healthcare context or environment on implementation strategies as well as the information, its presentation and individual behaviour change are all explored in this literature.

12.2 THE CONTEXT

The first theme from the qualitative analysis for the current project (chapter nine, section 9.2) was the *context*. The context of health care interventions is increasingly being seen as an important factor that influences their impact on outcomes (Foxcroft and Cole, 2000, Halladay and Bero, 2000, Iles and Sutherland, 2001, Plsek and Greehalgh, 2001, Dopson et al., 2002, Rycroft-Malone et al., 2002, Grimshaw et al., 2004). Different authors have considered elements of the context, from the contributions that quality assurance approaches may offer clinicians and researchers concerned with implementing evidence (Halladay and Bero, 2000 and Iles and Sutherland, 2001) to identifying what strategies (Grimshaw et al., 2004) or organisational features (Foxcroft and Cole, 2000) may promote the effective implementation of evidence, including research evidence, in clinical practice. Others have tried to discern patterns in healthcare contexts to determine their effect on implementing evidence or to develop models that may contribute to our understanding of the features or elements of contexts that promote or hinder the implementation of evidence in clinical practice (Plsek and Greehalgh, 2001 and Rycroft-Malone et al., 2002).

The *context* theme in the current study had an emphasis on changes, particularly in resources and the patient case mix. The history and the future of the research site were shaping influences. All these forces appeared to be influencing the research site's culture, however a strong cultural value of learning permeated the respondents' data and appeared to be a stabilising element in the otherwise changing culture. The researcher also shared this value of learning (see discussion of the category, understanding my implicit knowledge, in the theme *implicit knowledge of the setting* in section 9.8.2). The development of the researcher's thinking about the stabilising effect of the guideline was influenced by the respondents' data. The researcher had not anticipated how many respondents talked about the guideline as primarily useful for passing on practice, that is,

helping others learn. Hearing different perspectives on the changing context (discussed in more detail below) helped the researcher realise how fluid the context of patient care was. The combination of this and the learning theme led to the idea that shared values, such as learning, could thread through all the changes, giving some stability.

Cultural changes on the unit contributed to the need to maintain or change practice and it was thought a guideline might help (chapter nine, section 9.2.2). The ongoing nature of these cultural changes demonstrates how dynamic the context of health care environments can be. In this case the changes concerned skill mix changes, practice background changes of clinicians and case mix changes. The changing context at the research site had influenced the decision to develop and implement an updated guideline.

Halladay and Bero (2000) suggest implementing research in practice is beginning to be conceptualised in the context of organisational change. They draw from quality assurance literature to discuss how various strategies could inform the implementation of evidence in clinical practice. This discussion has an emphasis on implementation of evidence being seen in terms of projects that require a change that needs to be managed, whereas a strong feature of the current study's *context* theme is that the whole context in which the guideline implementation took place was changing. It was some of this change that also prompted the review of practice that led to the guideline development and implementation project.

Iles and Sutherland (2001) note the continually changing environment of the United Kingdom's National Health Service (NHS) in their review of the literature on change management and application to the NHS. The focus of this review, however, is on theories, models and programmes used for planned changes. A number of these, such as systems thinking, recommend viewing an organisation as a complex entity made up of

interdependent parts that need to be considered in the process of planning and implementing a change. Many of these models and theories do not as yet have a strong empirical evidence base, with many papers being based on a single case study that lacks rigorous evaluation. Total Quality Management (TQM) is one model where there are a number of rigorous research studies, including some in health care settings. Although a number of papers about single cases discuss positive outcomes, a number of research studies indicate no significant outcomes of such programmes (e.g. Shortell et al., 2000) and others recommend that better implementation is needed (Iles and Sutherland, 2001).

Dopson et al. (2002) found that context was considered an important influence and that many context-specific factors influenced the adoption and diffusion of knowledge, in their rigorous systematic review of qualitative studies about the diffusion and adoption of new ideas in healthcare settings. The studies included in the review used similar theoretical bases, were attempting to answer similar questions and used similar methodologies (i.e. case study based methods). There were, however, no discernable generalisations or patterns of diffusion, in Dopson et al's (2002) context theme, to enable the identification of the influence of specific contextual issues. This finding offers no insights into the *context* theme of the current study, other than reinforcing that the context is influential when implementing new knowledge in clinical practice.

Plsek and Greenhalgh (2001) suggest that because health care is so complex, in terms of the interdependence of clinical practice, research, education, continuing education, organisation and information management, conceptual frameworks that capture this complexity are needed to take research forward. Kitson et al. (1998) contribute to the debate about getting evidence into practice by presenting one such conceptual framework, which seeks to define and identify the interplay of different elements of practice that

influence the adoption of evidence in clinical practice in nursing. They consider that successful implementation of evidence and a resulting change in practice, is a function of evidence, context and facilitation. They suggest that all the elements of the framework should be considered simultaneously as they occur simultaneously in practice while evidence is being implemented and that they all impact on that process.

The concepts in the original model (Kitson et al., 1998) have been more rigorously developed through a concept analysis using seminal texts and healthcare literature (Harvey et al., 2002, McCormack et al., 2002 and Rycroft-Malone et al., 2002). The model or framework shows the three main concepts each of which have several categories that are presented on a continuum (Figure 12.2). The categories are mostly presented on a high to low continuum, illustrating elements of the categories that equate with the potential for successful (high) or unsuccessful (low) implementation of evidence in a practice setting.

Context again plays an important role. The context concept in the Rycroft-Malone et al. (2002) model and the *context* theme in the early extubation guideline qualitative analysis have similarities and differences. Both include cultural aspects. The values and beliefs of staff at the research site, particularly those related to learning (chapter nine, section 9.2.3 might be considered to be towards the high end of the Rycroft-Malone et al. (2002) culture continuum. Some other aspects of the culture at the research site might be placed towards the lower end of the continuum, such as the lack of clarity around boundaries and power and authority. At the research site there seemed to be some differences between the managers and the staff that emerged as part of the *tensions* theme (chapter nine, section 9.4.5).

The most evident cultural value that emerged from the current study's data was that of learning (chapter nine, section 9.2.3). Sharing knowledge and developing individuals' practice though learning appeared important. It may also have been a stable part of the culture, when other elements were changing. The majority of respondents considered a guideline that could help facilitate junior nurses learning the skill of early extubation was one of its objectives. Perhaps this objective, that is, to pass on and maintain practice, became the most useful aspect of the guideline. The lack of impact of the guideline on the outcomes in the interrupted time series analysis may not only be an indication that practice did not change, but also that it may have contributed to maintaining an established practice in a changing environment.

The Rycroft-Malone et al. model (2002) includes organisational influences in the context concept and other features such as leadership, and evaluation. These types of categories did not emerge from the current study as part of the *context* theme, but some of the elements, particularly when there were some that were on the high end of the continuum and some on the low end could be seen as resulting in some of the tensions identified in the *tensions* theme (chapter nine, section 9.4.5). For example, there appeared to be some lack of clarity in the relationships at the research site in the current study between the managers and staff (chapter nine, section 9.4.5). The issue of power and authority in the current study's findings seemed to show a lack of clarity around the boundaries of different roles. The project team were asked to implement the guideline, however the senior nurses appeared to hold a lot of power in the decision making. The project team did not always feel involved.

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The concept of leadership was not specifically explored in the qualitative analysis data regarding the early extubation guideline. This could be a limitation of both the researcher's perspective of a staff nurse, rather than as a manager, which meant leadership, was not a specific topic on the interview schedule. In this case, perhaps, demonstrating a lack of awareness because of the researchers' *implicit knowledge of the setting* (see chapter nine, section 9.8). The exploration of the topic is also limited by not having been conducted as a full ethnography. If it had been this issue, once identified, it could have been explored in further fieldwork. However, the qualitative interviews were flexible enough for the topic to have been explored if and when it was raised by the respondents. In spite of no specific exploration of leadership in the interview schedule, there was some data that related to leadership.

There did seem to be a change in leadership style in progress. It was an aspect of the category of historical context (chapter nine, section 9.2.1) in the *context* theme. Because the change appeared on-going, this led to a mixture of elements from the high and low ends of the Rycroft-Malone et al. (2002) concept of leadership. These issues could be explored in more depth in further research, perhaps using a full, applied ethnography, using a guideline implementation to explore the impact of leadership style. Perhaps it was the mixture of elements from both ends of the Rycroft-Malone et al. (2002) continuum for context at the research site that contributed to the tensions identified as a theme in the current study.

The *context* theme in the current study included the topics of where the unit had come from and where it was going. These were the category of the historical context (chapter nine, section 9.2.1) and the category, the future (chapter nine section, 9.2.4). For example, the practice of nurse-led early extubation was already well established at the research site

(chapter nine, section 9.2.1) and was part of its history. They also demonstrated the continual change and evolution of the practice context. These categories of history and future do not easily fit with Rycroft-Malone's concept of context. Neither does Dopson et al's (2002) theme of context as an influence add any further insights.

12.2.1 Summary of the Context Theme Discussion

The categories, historical context, the future and cultural changes give a clear sense of movement and demonstrate the dynamism of the clinical practice environment at the research site during the implementation of the early extubation guideline. Many of the changes raised by the respondents in the current study were more to do with changes in the structure of the environment where they worked, rather than changes caused by the implementation of the guideline. That is, they were linked to resources and workload (the historical context, cultural changes and the future), as well as values (the learning culture and the practice background changes, which influenced practitioners practice preferences) that influenced the process of the development and implementation of the guideline. In contrast, the discussion in the literature focuses on the changes that a project, such as implementing a clinical guideline, brings with it and how to manage these changes most effectively. The changes associated with the guideline itself, in the current study, perhaps emerged more clearly as some of the tensions that emerged from the theme of the same name (see discussion in section 12.4).

The implementation of the early extubation guideline was affected not only by how it was implemented (see discussion of the *process* theme, section 12.3) but also by the context in which it was implemented. The implementation itself seems to have prompted, as well as been part of, change at the research site. Although the guideline itself did not appear to

change the practice of early extubation, the process of bringing it in caused a lot of discussion and appeared to challenge previous ways of bringing in practice developments as part of a changing management style and a changing practice culture. It may have contributed to maintaining practice through education, which appeared to be a stabilising cultural value in a changing context. The guideline also gave the managers and staff involved cause to think about how to improve the process in the future, including organisational structures to facilitate the process. These last two points are explored further in the following discussion of the second theme, the *process*.

12.3 THE PROCESS

The theme the *process* had five categories. The description is not discussed here, as it was simply a description of what happened and is illustrated in chapter nine, Table 9.2. The categories, the product and emergent process give important insights into the interrupted time series results. These and the other categories, team working and communication, are also discussed in relation to the literature.

12.3.1 The Product

The product category of the theme the *process* (see chapter nine, section 9.3.6), gives some insight into why the guideline did not change practice, as measured by the outcomes in the interrupted time series (see chapter eleven, section 11.5). The final document was considered a consensus of local opinion about the practice of early extubation (chapter nine, section 9.3.6a). Experienced nurses found that their existing practice was accommodated by the guideline (chapter nine, section 9.3.6c). The researcher's potential impact on the guideline development and implementation was explored in the themes of *areas of potential influence* (chapter nine, section 9.6) and *presenting a balanced*

perspective (chapter nine, section 9.7). The respondents' views that the researcher had probably not biased the project and the researcher's efforts to present a balanced perspective and not to unduly influence the guideline content may be supported because the guideline was considered a consensus of local opinion. The researcher's task of giving a balanced perspective however, would have been more complicated had the research evidence been stronger.

The lack of research evidence appeared not only to contribute to tensions in identifying best practice (see section 12.4), but it also contributed to the consensus of clinicians' opinions being used as the basis of its content. The elements of what constitutes a high-quality guideline have been discussed and studied (Lohr and Field, 1992, Shekelle et al., 1999, Liberati et al., 2001, McSweeney et al., 2001, Graham et al., 2000). This discussion includes the role of research evidence, which is thought makes an important contribution to guideline quality. A guideline that is based on local consensus is considered to be more easily open to bias than one based on high quality research evidence (Grimshaw et al., 1995, Thomas et al., 1999a, Thomas et al., 1999b, Thomas, 1999c, Woolf et al., 1999 and Garfield and Garfield, 2000). This has implications for the early extubation guideline, which could not be based on high-level research. The National Institute for Clinical Excellence (NICE) (2001) recommends a process of guideline development that includes grading the available research evidence and using a robust, formal consensus process to agree guideline recommendations, particularly where research evidence is lacking. Although the early extubation guideline was considered by respondents as a consensus document, the development process was an informal, emergent one (see section 12.3.2), which means the potential for bias was greater than had the process been a more formalised one.

Grimshaw et al. (1995) in their systematic review of clinical guidelines for physicians suggested that high quality clinical guidelines need to be valid and avoid bias and that individual clinicians' interests can easily bias the content of guidelines. It is difficult to assess what bias the opinions of the clinicians at the research site may have introduced into the clinical guideline without high quality research evidence for best practice in early extubation with which to make comparisons. The results of the interrupted time series analysis (chapter eight) indicate that practice did not change. The lack of research evidence did mean that different opinions were allowed to influence the process of developing the guideline and a single way of practicing was not agreed on. The resulting compromise of having two options meant experienced nurses did not feel they needed to change their practice.

The evidence base for the guideline was not clearly written into the documentation. A number of respondents who were not involved in the development or implementation of the guideline commented that they assumed the project group had based it on evidence, but none commented that they knew exactly what the evidence was or how strong it was (chapter nine, see the end of section 9.4.1). The lack of documentation of the evidence for the guideline means it would be difficult for other clinicians to reproduce it and this has implications for its validity. The quality of the evidence base for the recommendations in the guideline needs to be clear (Lohr and Field, 1992, National Health Service Centre for Reviews and Dissemination, 1994, Grimshaw et al., 1995, Thomas et al., 1999a, Thomas et al., 1999b, Thomas, 1999c and Garfield and Garfield, 2000, NICE, 2001). The quality and the validity of the early extubation guideline could have been improved by using clear

grading criteria for the evidence it was based upon and by using a formalised consensus process to agree its recommendations for practice (Black et al., 1999).

The lack of information in guidelines developed by nurses seems to be a common problem. Thomas et al. (1999a, 1999b, 1999c) reviewed 18 studies that had evaluated the effectiveness of clinical guidelines in nursing, midwifery and allied health professions, from 1975 to 1998. They found that it was not possible to tell what the evidence base for most of the guidelines was. For example, where a literature review was used, little information was reported about how systematically the review was conducted, or about any quality criteria used to judge the literature. This means that the validity of the guidelines is questionable. The most common source of the guidelines was the consensus of local clinicians, as was the case with the early extubation guideline. There was generally little information on the identity of the clinicians involved in the development, in Thomas et al's review (1999a, 1999b,). This lack of information in guidelines may also be an indication that many nurses and allied health professionals would benefit from more training or support from experienced guideline developers. The importance of training is discussed further in section 12.3.2.

Dopson et al's (2002) review, described above in section 12.2, identified some themes that were connected with the evidence base of clinical guidelines. The theme, the enactment of evidence has some clear similarities with the findings of the current study. Dopson et al. (2002) found that where there was a lack of good quality evidence, as in the case of the early extubation guideline, the contestable evidence (i.e. what was best practice for early extubation) was used after much debate and negotiation (chapter nine, section 9.4).

Dopson et al. (2002) also mention that the cost of the change, in terms of the comparability between clinicians' existing knowledge and experience and the new knowledge, also impacts on how the evidence is used. The early extubation guideline negotiations resulted in little or no change being required of the clinicians and their experience was acknowledged as a key source of evidence for the guideline.

Other research too has found that strategies to implement guidelines that clinicians can easily relate to can be successful. Grimshaw et al. (1995) investigated the effectiveness of different implementation strategies in a systematic review. Although they did not find sufficient evidence to recommend particular implementation strategies, they found that strategies that were close to the user and that were closely related to clinical decision making were most effective and most successfully implemented.

Foy et al.'s (2002) research study seems to expand this finding. They conducted an observational study within the context of a national audit and feedback programme in Scotland. Evidence based clinical practice recommendations for gynaecological care were developed and circulated. Sixteen hospitals were audited and given feedback over an eighteen month period. An expert panel of gynaecologists was used to rate the recommendations according to 13 attributes that had been previously developed and tested. One finding adds an interesting slant to Grimshaw et al.'s (1995) idea that closeness of a guideline to the user is associated with more successful implementation. Foy et al. (2002) found that the clinical practice recommendations that were incompatible with clinicians' values were associated with lower compliance rates than those that were compatible with clinicians' values. The less compatible recommendations were, however, associated with significantly greater changes in practice. This seems to have similarities with the early

extubation guideline that was widely used within the context of the clinician's cultural value of learning as an educative tool, but it did not change practice. The use of retrospective audit data in Foy et al's study (2002) may have introduced significant bias and means that the generalizability of the findings is limited.

All the clinicians interviewed as part of the current study accepted the early extubation guideline. The experienced practitioners clearly felt it was compatible with their own practice. If Dopson et al's (2002), Grimshaw et al's (1995) and Foy et al's (2002) findings are correct, this could be one reason why the early extubation guideline appeared to be well used at the research site. However, the guideline did not require the clinicians to change their practice (chapter nine, section 9.3.6a). If it had changed practice the results might have been different.

In the *process* theme, the realisation of objectives (chapter nine, section 9.3.6b) and the usefulness of the guideline (chapter nine, section 9.3.6c) were also part of the product category. The impact of a guideline on patient outcomes is not only affected by the quality of the guideline itself, but also how effectively it is implemented. Even if the early extubation guideline had been developed to the highest standard, if the clinicians at the research site did not use it, the guideline would have had no impact on patient outcomes. From the evidence of the qualitative interviews it seems that the guideline was used on the unit and was apparently successfully implemented.

All of the respondents, particularly those who had not been involved in the development of the guideline indicated that they used the guideline. Many experienced practitioners commented that they checked whether their existing practice fitted with the guideline

recommendations. They felt they did and so considered their practice was within the guideline. For inexperienced nurses the guideline had been used to learn the skill (chapter nine, section 9.3.6c). It seems that the guideline was used on the unit, certainly by all the nurses interviewed who were selected to represent a cross section of unit staff. However, one respondent raised the point that it was difficult to assess whether people actually used the guideline, because they did not see people using it, i.e. looking at the written guideline. The limitation of observing nurses looking at the guideline as a measure of whether they used it, is that many of the respondents said that as nurses became more skilled they did not look at the guideline because it was instilled in their memory. The nurses also seemed to use the guideline when teaching inexperienced nurses how to extubate patients (chapter nine, section 9.2.3). This also indicates that the guideline was actively used on the unit.

It seemed that, although the guideline had originally been considered as a way of improving a perceived increase in ventilation times, its main role came to be seen as educative. The guideline was viewed as a useful teaching tool, particularly to help inexperienced nurses develop their skills. This change in the focus of the guideline means that its main effect may have been on training inexperienced nurses in the skill of early extubation to maintain the existing standards of practice on the unit. Further investigation is needed to substantiate this suggestion. It is also interesting that the value placed on learning in the culture of the unit (see 12.2 for the discussion of the *context* theme) also clearly affected the use of the guideline and education was seen as an important role for the guideline.

Educative strategies, such as educational outreach visits, use of an opinion leader, interactive educational meetings, marketing strategies, reminders, or combinations of these

for implementing evidence in practice have had varying effectiveness in different studies (Grimshaw et al., 1995, Oxman et al., 1995, Bero et al., 1998, Grimshaw et al., 2004). However, it is interesting that the nurses at the research site, who had learnt about the guideline through internally organised education sessions were not only using it but had also clearly adopted it as a tool for educating new members of staff. The majority of the members of staff appeared to see passing on practice as part of their established role. This may be related to Kitson et al's (1998) and Harvey et al's (2002) points that practice development changes may be longer lasting when clinicians from the practice area take on facilitation roles. This seems to have happened in this project, although it does not seem to have been a particularly conscious or planned part of the implementation process. The whole process was an internal development, but the fact that it was not only members of the project team who used the guideline, indicates that the project team had successfully engaged the whole nursing team in using the guideline. Perhaps this also shows the influence a cultural value, that is part of the context, can have on an implementation process.

The category, completion of the project, in the theme *areas of potential influence* (chapter nine, section 9.6.2) raises the question of whether the uptake of the guideline would have been so good if the research project had not happened. A few respondents felt that the research project had increased interest in the guideline development and implementation and one respondent's felt this had given impetus to the team to complete the project. It is not possible to be sure what impact the research actually had on the use of the guideline, or indeed its development and implementation. However, it is worth bearing in mind the impact could have been significant, although only one respondent specifically raised the issue of the research influencing the completion of the project.

The fact that the guideline did not require a practice change however permeates all these discussions. Whether the implementation would have been so successful if it had challenged the status quo is difficult to assess. The Cochrane Collaborations' Effective Practice and Organization of Care (EPOC) group have suggested that maintaining the status quo is an important factor in resisting change (National Health Service Centre for Reviews and Dissemination, 1999). So it could be argued that the reason practice did not change was because of clinicians' resistance resulting from the need to maintain the status quo. It is difficult to know the extent to which the need to maintain the status quo influenced the guideline development and implementation because there was no strong research evidence to challenge practice, nor was a robust, formal consensus process (NICE, 2001) to agree the guideline's content, that might have required a change in practice and change the status quo.

12.3.2 Emergent Process

Some elements of the process of implementation may have contributed to the reason why the early extubation guideline was a consensus document. These can be seen in the emergent process (chapter nine, section 9.3.2). The two areas that emerged in the analysis that contributed to the responsive nature of the *process* were lack of planning for difficulties and the lack of a formal approval and review process. The latter could also be considered an organisational factor, as it was a lack in the organisation of the unit that was acknowledged as causing some difficulties in the implementation process. Organisational issues could also be regarded as part of the context. Historically the research site did not have organisational structures they identified during the course of the extubation guideline

development as necessary to support such developments in the future. This is also an example of the interplay between the *process* and the *context* themes.

Although the project group had planned some of the implementation process (chapter nine, section 9.3.2a), this process was also significantly influenced by situations that arose. Iles and Sutherland (2001) acknowledge that emergent aspects are part of change processes, whether the change is entirely spontaneous or meticulously planned. An example of the responsive or emergent nature of the early extubation guideline project, that relates to the lack of planning sub category, concerns piloting the guideline.

Although a pilot was not planned, the discussion and subsequent revisions of the guideline, following the teaching sessions (chapter nine, section 9.3.1) played a similar role to a pilot. Grimshaw et al. (1995) consider that a pilot helps to increase the validity of the guideline and NICE (2005) include a pilot as one of their recommended stages of guideline development and implementation. So, although these events were not planned they may have contributed to the quality of the guideline, increasing its validity.

Another area where the project team did not appear to have planned strategies was for tackling people's resistance to change. The effects of the resistance to change encountered in the implementation of the early extubation guideline is explored further in the discussion of the theme of *tensions* in section 12.4.

One reason for the lack of planning could be that the project team did not appear to have specific, previous experience of implementing a guideline, although some respondents mentioned they had studied some aspects of change management or demonstrated

awareness of theories of how nurses learn skills (see the end of section 9.2.3, in chapter nine).

The nurses also expressed some uncertainty in their research appraisal skills, which are needed to identify the research evidence base for the guideline (see chapter nine, section 9.4.1). Although some respondents expressed uncertainty about their research skills, some mentioned that they felt the researchers' skills were seen as a resource to the project (chapter nine, section 9.6.3). The data indicated that the researchers' skills were seen as generally useful, but were not specifically related to how well the research was appraised for the early extubation guideline. This may indicate a lack of understanding of the process of guideline development on the part of the respondents who were not able give specific information whether or not the researcher's skills impacted on the quality of the project team's literature review. It could also have been an area the researcher could have explored more fully. Bias can be reduced from systematically reviewing the literature and synthesising the evidence. This will also increase the validity of the guideline. Grimshaw et al. (1995) and Garfield and Garfield (2000) suggest that not all guideline development groups will have the necessary skills to develop good quality guidelines and this has resource implications.

The inexperience of the team may account for the responsive nature and a number of issues were raised concerning the lack of planning for difficulties (chapter nine, section 7.3.2d) and particularly the issue of dealing with resistance to change (chapter nine, section 9.7.4). There were also some issues that may be explained by a recent change of managers or their inexperience, in particular, the lack of a formal approval and review process (chapter nine, section 9.3.2b).

Although the project team and the managers had learnt from the experience of implementing the guideline, it could be that they may have benefited from more training before they embarked on the project. The Cochrane Collaboration's Effective Practice and Organization of Care (EPOC) group reviewed individual and organisational measures to effectively implement evidence in clinical practice (National Health Service Centre for Reviews and Dissemination, 1999). One of their recommendations was that there is a need for more understanding of what makes an individual successful in influencing or managing change as a prerequisite for developing training for staff with clinical effectiveness responsibilities.

Thomas et al. (1999a, 1999b and 1999c) in their systematic review found little research evidence that could help the nurses at the research site identify successful implementation strategies to improve their process to improve the planning and review and approval processes. Thomas et al. (1999a, 1999b, and 1999c) found that research into guideline implementation in nursing, midwifery and the allied health professions was generally of poor quality and conclusions were difficult to draw because of poor methodology. They also found that different dissemination and implementation strategies were used but with little reference, in many studies, to reasons for choice of strategy or reference to the literature on such strategies.

Thomas et al. (1999a, 1999b and 1999c) did not find sufficient evidence to recommend particular dissemination strategies. However active strategies, such as having a designated expert or opinion leader for the implementation phase, seemed to be more effective than passive strategies such as distributing printed documentation to clinicians. Other research

has also investigated the effectiveness of using opinion leaders to help implement evidence in practice, although these have tended to focus on evidence in medical practice rather than specifically in nursing. The effect of an opinion leader on the success of the implementation in these systematic reviews appears varied (Grimshaw et al., 1995, Oxman et al., 1995, Bero et al., 1998, National Health Service Centre for Reviews and Dissemination, 1999 and Grimshaw et al., 2004).

The early extubation guideline implementation seemed to have been led by the practice development nurse and the project team leader, although it seems that managers instigated the project (see chapter nine, section 9.3.1). Unlike the idea of an opinion leader in many of the studies referred to in the literature, the leaders of this project did not appear to be identified by the local practitioners as opinion leaders in the sense of colleagues always looking to them to take a lead in best practice, although they were respected practitioners and the post of practice development nurse encompasses leading best practice. There appeared to be more of a team approach, with shared responsibilities for implementation. It could also be a result of an internal implementation, because the participants were already known to each other and were possibly negotiating new roles for themselves within the wider team during the course of the project. One respondent alluded to managers gradually changing their attitude to accepting that project team members were able and knowledgeable enough to take practice forward. The guideline implementation, rather than being led by one particular inspirational figure, was more of a local consensus process. Bero et al. (1998) found that using local consensus processes were variable in their effectiveness. The process could be considered successful in this case because of how well used the guideline appeared to be.

Perhaps facilitation skills may play a pivotal role in successful implementation strategies (Rycroft-Malone et al., 2002). These may or may not be invested in one person such as an opinion leader. The lead implementers of the early extubation guideline and other respondents at the research site identified skills they used and developed during the process of developing and implementing the guideline. These included diplomacy, negotiation, ability to compromise, understanding and tackling resistance to change, teamwork, education of colleagues, understanding of research evidence and practice, understanding and working within the organisational culture. These skills were used to facilitate the development and implementation of the early extubation guideline.

Harvey et al (2002) attempted to clarify whether facilitation is conceptually discrete from the other change agent strategies of opinion leader and educational outreach. They concluded that any distinction is not yet clear, suggesting that some differences may be in the use of internal (opinion leaders) or external facilitators (educational outreach), the use of marketing principles (educational outreach), or the focus of developing organisational culture and systems (facilitator). It may be that it is the facilitator's skills and role and their ability to use these flexibly that are the most important determinants of successful implementation of evidence in practice. It may be less crucial whether they are an educationalist, an opinion leader or a facilitator. However, the research evidence for which aspects of skill and role are the most influential is lacking and warrants further investigation (Harvey et al., 2002).

In the Rycroft-Malone model (Figure 12.2) (2002), the 'purpose of the facilitation' is used to define the type of facilitation. It ranges, on a continuum, from achieving a particular task to effecting a holistic change in the culture of the practice area (Harvey et al., 2002). Any

type of facilitation could be successful in implementing evidence and the categories 'role' and 'skills' and 'attributes' relate to the characteristics of the categories associated with successful facilitation, rather than one end of the continuum being high and the other low.

The results of some case studies (Kitson et al., 1998) that were used in the development of the model (Figure 12.2, (Rycroft-Malone et al., 2002) may suggest that the holistic end of the facilitation (purpose) continuum may result in more lasting changes, because it also has an impact on the context continuums (Figure 12.2). That is, if the facilitation is holistic, the changes it brings impact not only on the particular focus of a project, but also on contextual aspects of the clinical setting. In the case of the early extubation guideline project, the learning and negotiation processes that went on within the wider nursing team seem to have produced some organisational changes, i.e. the formation of a formal board to facilitate the process of implementing practice changes. Whether this was entirely due to the style of facilitation adopted by the project team leaders being holistic and enabling, in the sense used in Rycroft-Malone et al's model (2002), is difficult to judge without further testing of the model or investigation at the research site. Although some of the skills identified by respondents in the current research (diplomacy, negotiation, ability to compromise, understanding and tackling resistance to change, teamwork, education of colleagues, understanding of research evidence and practice, understanding and working within the organisational culture) could be categorised with project management or flexibility in role in the Rycroft-Malone et al. model (2002), it is perhaps these skills that were needed to resolve the tensions that the project team encountered.

12.3.3 Team Working and Communication

Other categories in the theme, the *process*, also emerged; team working and communication. Team working (chapter nine, section 9.3.4) within the project team was considered to have gone well and the multidisciplinary nature of the team was considered positive. Using a multidisciplinary team is considered to improve the quality of a guideline (National Health Service Centre for Reviews and Dissemination, 1994 and Graham et al., 2000). The multidisciplinary teamwork could be considered a planned aspect of the early extubation guideline development process. It contributed to the guideline quality by ensuring that views from different professions were incorporated. All the professions involved in extubation also agreed its use.

Communication (chapter nine, section 9.3.5) covered many aspects of the *process* from discussion within the project team, to consulting staff, communication between the project team and the managers to communicating the guideline itself through its content and format. Some aspects of communication worked well, others were thought to need improvement and caused some tension. Good and effective communication is a factor that could positively influence many aspects of guideline development and implementation (National Health Service Centre for Reviews and Dissemination, 1999). The data from this one research site seemed to indicate that the development and implementation was affected by difficulties in communication between the managers and other staff (see the *tensions* theme, chapter nine, section 9.4.5 for further details). This again could be viewed as not only a difficulty between individuals but also as the lack of organisational structures that could be altered to improve the process of development and implementation of a guideline.

12.3.4 Summary of the Process Theme Discussion

The theme, the *process*, seems to present a possible explanation for the reason the extubation guideline did not change the outcomes for the interrupted time series (chapter eight). The guideline did not appear to change practice. The reasons for this seem to be associated with the lack of research evidence and the effects of the consensus process used to develop the guideline. The guideline seems to have been successfully implemented because it appeared to be widely used. Whether this would have been so if the guideline had required nurses to change their practice is debatable. It is also possible that the research may have impacted on the implementation by giving an external impetus for interest in and, possibly, the completion of the project. The emergent nature of the process of development and implementation may have been a result of the inexperience of those involved. It highlighted some areas for improvement for future projects, in particular, the need for an organisational structure to facilitate the process of the project. A lack of planning for difficulties, such as how to tackle resistance to change, may also be an area that could be improved.

Although the extubation guideline did not alter the outcomes, it may have contributed to maintaining practice in a changing environment through its wide adoption as an educative tool. Learning, identified as a cultural value in the *context* theme, seems to have strongly impacted on the use of the guideline, identified in the *process* theme.

The three themes, *context*, *process* and *tensions*, are clearly interrelated from the above discussion of the *process*. The *process* was affected not only by the project teams conduct of the development and implementation of the extubation guideline, but also by the context and various tensions that were the result of contextual issues as well as interpersonal

differences. The effects of various tensions on the *process* have been mentioned in this discussion. They are explored in more detail below.

12.4 TENSIONS

The third theme from the qualitative data analysis was *tensions* (chapter nine, section 9.4). The categories that make up this theme were aspects of the implementation process where different opinions, demands or needs caused some tension that needed to be worked through. This theme seemed to capture some of the dynamism involved in the process of developing and implementing the early extubation guideline. The researcher's reflections indicated that the choice of word for this theme was influenced her implicit knowledge of the research site. The tensions the researcher experienced while working in her clinical role at the site contributed to her understanding and interpretation of this theme (chapter nine, section 9.8.2). The development of this theme owes much then to the practitioner researcher's perspective. It has value because the researcher felt she was drawing on a shared experience at the research site, which gives some validity to the theme. The insider perspective may also contribute to explaining why this theme is different from others in the literature, which predominantly appears to have an outsider perspective. However, the interpretation of the data in the *tensions* theme could be limited by seeing it only from an insider's perspective. It would be interesting to compare an outsider's perspective of the respondents' reported experiences. This is perhaps both a strength and limitation of the study.

12.4.1 Identification of Best Practice

The first category was the identification of best practice (chapter nine, section 9.4.1). It concerned the lack of research evidence for making the decision to extubate and supporting

the patients' breathing while making this decision. Best practice was not easily agreed on in the case of the early extubation guideline. There was a lack of high quality research evidence to indicate the best method of assessing patients' readiness for extubation and supporting their breathing whilst making this assessment. The literature review (chapter two) supports the research site nurses' view that research evidence was lacking. It found no discussion of this aspect of early extubation, except in the article by Gale and Curry (1999), where their unit adopted a flexible approach in their extubation algorithm because of the lack of evidence for best practice in this area.

The systematic review also found insufficient evidence for nurse-led early extubation to conduct an analysis comparing doctors' decision making for early extubation with that of other health care professionals, including nurses (chapter seven, section 7.3). The systematic review also shows that the evidence for the safety of the practice of early extubation itself could be improved and that the majority of it only covers part of the cardiac surgical population, with most studies covering only coronary artery bypass graft surgery (CABG) surgery (see chapter ten).

Woolf et al, (1999) suggest that clinical guidelines are most useful when research evidence can be used to clarify uncertainties in clinical practice. When research evidence is lacking clinicians will rely on their knowledge and experience, consensus opinions of other clinicians. Although, these methods of deciding clinical practice are used in conjunction with research evidence, when research evidence is of poor quality or lacking, or when clinicians have different experiences of what works, a consensus of best practice may be less easily agreed upon (Dopson et al., 2002).

The lack of research evidence meant the clinicians at the research site who developed the guideline relied on lower levels of evidence (Phillips et al., 2001). Their own experience played a significant role here. The tension between different practice preferences created debate (chapter nine, section 9.4.1) and the resulting guideline incorporated the different existing practices. The debate also led to a theme that emerged from the researcher's reflections, *presenting a balanced perspective* (chapter nine, section 9.7). The guideline was considered to be a compromise, by some respondents. It could also be regarded as a consensus of local opinion and experience (see chapter nine, section 9.3.6.a and the discussion about the category the product, in section 12.3).

Thomas et al's systematic review (1999a and 1999b) of clinical guidelines in nursing and allied health professions indicates that nurses and the allied health professions have been slower than doctors to use high quality evidence in both the content and the development of clinical guidelines. This may also be a reflection of the fact that nursing and the allied health professions have an ongoing need to develop research expertise and capacity (HEFCE, 2001). This last point is supported by the lack of research evidence the nurses at the research site found to incorporate into their guideline, rather than an unwillingness to use it.

The nurses at the research site also did not all seem experienced or confident in using the evidence they did find in their discussions (chapter nine, section 9.4.1). Appraisal of research is still an area where nurses could benefit from more education and experience. This point is related to the earlier discussion of the need for training and education for those with clinical effectiveness responsibilities in practice (see section 12.3.2).

The evidence concept from the Rycroft-Malone et al. model (2002) (Figure 12.2) provides some interesting comparisons for the early extubation guideline results. Evidence is given prominence in the Rycroft-Malone et al. model as a separate concept, whereas the evidence was part of the *tensions* theme, in the category identification of best practice (chapter nine, section 9.4.1), although there are also clear links with the product category of the *process* theme. That is, the lack of research evidence contributed to the consensus process that produced the guideline.

The concept of tensions may capture the dynamism of the process of finding, weighing and using evidence, whereas the strength of the continuum, in Rycroft-Malone et al's model (2002), is that it identifies the different aspects of the concepts related to evidence, its use and what features facilitate or work against its use.

In the Rycroft-Malone et al. (2002) model, working through different high and low aspects of the categories could cause tensions. For example, at the research site clinical experience was valued (high on the continuum), but a consensus was reached by some compromises on different practice preferences, rather than each being tested by groups as suggested on the related continuum.

Dopson et al. (2002) identified several themes related to evidence. These themes concern the dynamic processes involved in implementing or diffusing evidence in practice. Some of these themes offer some insights into the tensions created during the identification of best practice at the research site.

One of Dopson et al's (2002) themes was robust evidence is not sufficient to facilitate diffusion. Interestingly they considered that there is a weak relationship between the strength of the evidence base and clinical behaviour change. There was not a strong research evidence base for the early extubation guideline and the guideline did not require a clinical behavioural change. It is not possible to know whether Dopson et al's (2002) points would apply to the research site in the current study without further investigation. If they do, it could be that had there been stronger research evidence the guideline still might have ended up as it did.

Another theme in Dopson et al's (2002) work is that the interpretation of evidence is socially constructed. There are competing bodies of evidence and individuals, groups and or professions can interpret these differently. The priority given to evidence can change over time and controversy can persist affecting adoption. Practice experience seemed to provide most evidence for the extubation guideline. There were two competing methods of assessing patients. These did seem to be socially constructed by the practice background experience of the clinicians, either theatre recovery or intensive care unit (chapter nine, section 7.2.2). The researcher's own views of her practice evolved and were clarified by the debate about practice from her own practice background culture to practice in light of the debate (chapter nine, section 9.7.1). Some respondents also felt that clinicians did not use research evidence impartially (chapter nine, section 9.4.4).

Evidence from patients is identified as a component of the Rycroft-Malone et al. model (2002). Patients were not included in the development of the extubation guideline and none of the respondents raised this as an issue. Thomas et al. found that having no patient involvement was the case for most guidelines they reviewed (1999a and 1999b). The

reasons why patients' views were not sought for the early extubation guideline is not evident in the data, and could be explored in future research, by including the topic on the interview schedule. It may be that the nurses assumed that as patients were still affected by anaesthesia during the period of postoperative ventilation and extubation they may not remember the process because of the amnesic properties of anaesthesia and so their views were not sought. It may also be a reflection that raising awareness of including patients in developing guidelines and in research is a recent development in the United Kingdom and had not yet become a routine part of practice considerations for the early extubation project group, or for those who developed the guidelines reviewed by Thomas et al. (1999a and 1999b). NICE (2005), reflecting current policy influences on increasing patient involvement in healthcare, recommends patient and user involvement as a specific stage in the guideline development process.

It may be that the lack of research evidence meant that best practice was unclear, but a flexible but useful guideline (chapter nine, section 9.4.2) was considered important by clinicians. Personality and resistance to change (chapter nine, section 9.4.4) also played a part in how the guideline developed as a consensus document.

12.4.2 Flexibility Versus Rigidity

The second category of the theme *tensions* was flexibility versus rigidity (chapter nine, section 9.4.2). The tension between writing down practice to ensure safe standards and, at the same time, allowing for clinicians to use their own judgement, was an issue for the nurses at the research site. Most respondents considered promoting flexibility and discouraging prescriptive practice important. Perhaps, associated with the tension of flexibility versus rigidity, is the category of the tension between the needs of the expert

versus the needs of the novice (chapter nine, section 9.4.3). The connection is that an experienced clinician would be more likely to want to use clinical judgement in extubating a patient compared to an inexperienced nurse who would need more concrete guidance to practise safely (Benner, 1984). This local debate about flexibility versus rigidity reflects a similar debate in the literature related to clinical guidelines, particularly in the medical literature. Clinical flexibility is also considered a quality indicator for clinical guidelines (Lohr and Field, 1992, National Health Service Centre for Reviews and Dissemination, 1994 and Graham et al., 2000).

In the literature, concern about clinical guidelines among clinicians, particularly in medicine, seems to focus around the need for flexibility in clinical practice. This too was a concern for the nurses at the research site. The idea of clinical guidelines is perceived, by some, as too prescriptive for the real world of clinical practice (Hart, 1993, Haycox et al., 1999 and Garfield and Garfield, 2000). Concerns raised include a restriction on autonomy; the potential for defensive medical practice if local commissioners insist particular guidelines are used; narrow interest groups influencing the content of guidelines so only particular aspects of care are covered (Haycox et al., 1999); a lack of effective evaluations of outcomes and costs which could distort decision making (Haycox et al., 1999) and (Garfield and Garfield, 2000).

Two of these concerns were issues at the research site. There were concerns on both sides of the debate that one practice preference would dominate, but the negotiation that was part of the implementation process ensured that this did not happen. The researcher was aware of this issue and her reflections resulted in attempts not to be seen as favouring one practice over the other (chapter nine, sections 9.7.2 and 9.7.3). Both practices were incorporated

into the guideline in the absence of research evidence demonstrating that one was better than the other. Evaluation did not appear to be a strength of the research site team, possibly relating to the need for more training for healthcare professionals with clinical effectiveness responsibilities. Perhaps it is another area where an organisational structure to promote and monitor audit could be beneficial.

The discussion in the literature about the issues of standardising quality care and the need for clinical judgement seems to be changing views on both sides of the debate. Proponents of clinical guidelines make it clearer what clinical guidelines can and cannot do (NICE, 2001). There is also some evidence (Grilli et al., 1999) that clinicians' attitudes towards practice guidelines are changing, with a statistically significantly greater proportion of clinicians' favouring the use of research evidence, as opposed to clinical experience, as the main basis of clinical guidelines (43% in 1993 and 57% in 1997). Although a reasonable response rate to both surveys (57%) was achieved and the findings are interesting, their generalizability is limited to the population of Italian Oncologists. For nurses, the lack of available research evidence may mean that the challenge to the established practice of using clinical judgement as the main source of evidence has not yet been as strong as it has in medicine.

Garfield and Garfield (2000) point to concerns that implementation lags behind guideline development, with the risk of recommendations not being based on current evidence. Evidence from randomised trials does not reflect the complex contexts and complexity of many patients' conditions in which clinical decisions are taken. Although the systematic review (chapter seven) showed that much of the evidence for early extubation, in terms of morbidity and mortality outcomes, was limited to a portion of the cardiac surgical patient

population (i.e. patients undergoing routine coronary artery bypass grafting) and that practice has moved on since those studies were published (chapter ten), the lack of research seems to be a more significant problem for nurses and allied health professionals (see discussion in section 12.4.1).

The lack of current evidence for the nurses at the research site meant that they used current practice experience for the guideline. There was no conflict with research evidence as it was not available. The guideline appeared flexible enough for the nurses to use for a wide variety of patients they nursed (not just those having CABG surgery). The algorithm design also incorporated guidance on what to do if the patient was not meeting the parameters for extubation, which allowed for reliance on clinical judgement for such patients.

In nursing there are also concerns over the possible tension between clinical judgement and guidelines (Hewitt-Taylor, 2003), and (Wilson, 1999). However, using and practising within policies and standards of care may be more acceptable in the nursing mind than it is in the medical mind. Manias and Street (2000), in their ethnographic study of nurse to nurse and nurse to doctor relationships in a 16-bed Australian critical care unit, found that nurses tended to use written guidelines, policies and protocols to legitimise their knowledge, particularly when they did not agree with medical decisions about care. Doctors on the other hand, placed more value on autonomy and professional authority than on written guidance. This rigorously conducted ethnography provides interesting qualitative research evidence that may be recognisable to practitioners in different settings. It also provides some theoretical understanding of the use of written guidance by nurses

and doctors. These theories need to be tested in quantitative research before they can be generalised to all nurses and doctors in western healthcare settings.

Practising within written guidance, such as patient group directives, has also allowed nurses to extend their roles. This has been seen as a positive development for the profession (Department of Health, 1993 and Department of Health, 2000b). Allen and Scott (2003) in their review of evidence for models of primary and secondary prevention of coronary heart disease, report that nurse case managers were more likely to follow drug management algorithms than physicians.

Using written guidance to legitimise their knowledge (Manias and Street, 2000) and to extend their roles (Department of Health, 2000b) may account for why nurses are more likely than physicians to follow written guidelines (Allen and Scott, 2003) and consequently why there is less debate in the nursing literature about clinical guidelines infringing on clinical judgement. Alternatively, if as Thomas et al. (1999a and 1999b) found, the majority of clinical guidelines in nursing are not based on high quality research evidence, they are more likely to be based on a local consensus. By implication, local clinical judgement and opinion may therefore be the main basis for the majority of nursing guidelines, thus accounting for less discussion about threats to clinical judgement in the nursing literature posed by clinical guidelines.

The nurses at the study site clearly considered research evidence to be an important part of developing their guideline, but were hampered by a lack of research evidence. It may be that nurses are much more aware now of using research than when the majority of studies

in Thomas et al's review (1999a and 1999b) were conducted, but that a lack of high quality research into nursing practice may be the more significant problem.

The way the debate about flexibility versus rigidity became apparent during the process of implementing the early extubation guideline was in the discussion of terminology (chapter nine, section 9.4.2). The guideline had originally called the guideline a protocol, but felt that the term protocol was associated with prescriptive practice, so they adopted the term guideline.

Thomas et al. (1999a, 1999b and 1999c) found that the name given to the guidelines (protocol, guideline, local guideline etc.) varied and seemed to be based on personal preference. This finding corroborates the premise of Duff et al's (1996) work and Mulhall et al's (1997) comments that the terms are often used interchangeably. Guidance is used for a wide variety of practice areas and this may contribute to differing use of terms.

Providing guidance in clinical practice can range from nationally, or even internationally, developed guidelines for specific medical conditions to local guidance for a specific healthcare practice, such as changing a dressing on a central venous catheter. Guidance is also linked with quality assurance such as standard setting and practice policies.

Guidelines are also associated with detailing certain parts of care pathways. Algorithms and protocols are often used as reference documents for recommended or preferred practice.

This can be for specific events such as a cardiac arrest or as a specific description of a clinical practice. The boundaries between these different aspects of practice overlap and this has led to some confusion about terminology in nursing practice. The terms guideline

and protocol, and, to some extent, algorithm, policy and standards, are often used interchangeably (Mulhall et al., 1997).

As useful as the definitions are, terminology in practice areas appears to remain variable. For the nurses at the research site the debate about terminology was closely linked with wanting the guideline to be flexible rather than prescriptive to allow room for clinical judgement to be used (see chapter nine, section 9.4.2).

12.4.3 Resistance to Change

Resistance to change was another tension that featured in the early extubation guideline implementation (chapter nine, section 9.4.4). Resistance came in the form of individual resistance to changing practice. In some respects this seemed related to the lack of evidence to support one practice over another, although the use of evidence to support practice did not always appear to be equally valued for a clinician's practice preference compared with the alternative practice. It seemed, to some respondents, hard for experienced practitioners to change their practice, with other more junior staff seeming to find it hard to accept their experience as a valid form of evidence. Personality was considered to play an important role in conflicts.

The literature on guideline implementation has also considered strategies to promote changes in clinicians' behaviour and has linked this to various implementation strategies. Many interventions have been the subject of research and the Cochrane Collaboration's Effective Practice and Organization of Care (EPOC) group have developed a useful taxonomy of professional interventions to help classify these interventions (Grimshaw et al., 2004, p8).

Some of these interventions have already been discussed in relation to the theme the *process* (section 12.3), such as making sure that practice developments like a guideline are close to the clinicians, education initiatives, the use of an opinion leader or facilitator (see above in *process* theme discussion section 12.3), combinations of strategies and strategies that specifically identify and tackle resistance to change.

An issue raised in the emergent process in the *process* (chapter nine, section 9.3.2 and discussed in section 12.3 above) was that the team did not appear to have made plans for how to tackle resistance to change and they appeared to respond to issues as they arose. This illustrates the link between the themes *tensions* and the *process*. The project team could have considered strategies to tackle resistance to change before implementing the guideline, although the literature does not reveal clearly what the best strategies are.

Much of the research to identify the most effective strategies for implementing research or clinical guidelines in practice has been the subject of systematic reviews that have been published over the last decade (Grimshaw and Russell, 1993, National Health Service Centre for Reviews and Dissemination, 1994, Grimshaw et al., 1995, Oxman et al., 1995, Bero et al., 1998, National Health Service Centre for Reviews and Dissemination, 1999, Thomas et al., 1999a, Thomas et al., 1999b, Foxcroft and Cole, 2000, Grimshaw et al., 2004). The later reviews demonstrate the growing awareness of the complexity of research implementation by not only focusing on strategies aimed at simply changing individual clinicians behaviour but also focusing on strategies that consider organisational contexts (Foxcroft and Cole, 2000) and economic or cost effectiveness considerations (Grimshaw et al., 2004). It seems to be the case with the current research that the complexity of the

context and the *tensions*, whether related to organisational features of the research site or individual practitioners opinions, practice preferences and personalities, all played interdependent roles in the process of implementing the guideline.

The reviews mentioned above contribute to the knowledge base for the effectiveness of strategies aimed at changing clinicians' behaviour. A constant theme of these reviews is the lack of high quality research to enable clear recommendations to be made. However, a number of implementation strategies and their links to theories of behaviour change have been considered.

Many of the systematic reviews have investigated the effectiveness of implementation strategies to change clinicians' behaviour. The premise being that, if you want a clinician to adopt an evidence-based clinical guideline, it is likely to involve a change in their behaviour. The theoretical basis for promoting a change in clinicians' behaviour that results in the effective implementation of research is also not yet clear. Few of the studies explicitly linked their findings to behavioural change theories (Bero et al., 1998) and although different models or theories, such as learning theory, social cognition models and models of organisational change, can be identified in studies (National Health Service Centre for Reviews and Dissemination, 1999) more research is needed to better understand the links between implementation strategies and behaviour change theory.

The EPOC group (National Health Service Centre for Reviews and Dissemination, 1999) suggests further work is needed to assess dissemination strategies against outcomes such as knowledge, attitudes and beliefs of the targeted clinicians because of the interplay between these and behavioural change. The EPOC group suggests that the way ahead for

investigating implementation strategies is by seeking to understand professional behaviour when faced with specific barriers to change and then assessing the effectiveness of strategies targeted at removing those barriers. More understanding of what makes an individual successful in influencing or managing change is also highlighted as a prerequisite for developing training of staff with clinical effectiveness responsibilities. Modelling successful elements of facilitating practice developments has been an area of study for the group from the Royal College of Nursing (Kitson et al., 1998 and Rycroft-Malone et al., 2002) discussed earlier in section 12.3.

Thomas et al (1999a, 1999b and 1999c) did not find any evidence to determine whether effective strategies for changing physicians' behaviour, such as those identified in systematic reviews that have focused on medical practice (Grimshaw and Russell, 1993, Grimshaw et al., 1995, Oxman et al., 1995, Bero et al., 1998, National Health Service Centre for Reviews and Dissemination, 1999 and Grimshaw et al., 2004), were also effective for nurses, midwives and allied health professionals. Thomas et al. (1999a, 1999b and 1999c) conclude that research into effective implementation strategies for clinical guidelines in nursing and the allied health professions is still in the early days and clinical guidelines are often not implemented within evaluative frameworks. More research is needed before any conclusions about the effectiveness of different implementation strategies can be drawn. It may have been, not only a lack of forward planning, but also a lack of evidence for the most effective strategies for promoting change, that meant the nurses at the research site did not appear to include any strategies for tackling resistance to change in their implementation plan. It also seems that the skills for dealing with resistance to change may be important in the light of the lack of a strong evidence base for effective strategies. The skills of diplomacy, negotiation, ability to compromise,

understanding and tackling resistance to change, teamwork, education of colleagues, understanding of research evidence and practice, understanding and working within the organisational culture that respondents identified (discussed in section 12.3) appear to have enabled the guideline to be implemented.

12.4.4 Differences Between Managers and Staff

The final category in the *tensions* theme was the differences between the managers and the staff. It could simply be that the data showed the different views because of the different roles and responsibilities of each group. However, the differences appeared related not only to their views of the process, but also a lack of clarity in roles and responsibilities and communication between the two groups. Effective communication was identified in EPOC group's review (National Health Service Centre for Reviews and Dissemination, 1999) as an issue that promoted effective implementation strategies. The board that was going to be set up to facilitate the process of implementing such practice developments may help clarify some of the issues and positively influence the communication processes.

The researcher felt that her own experience and perspective as a staff nurse might impact on the interpretation of the data relating to these differences (chapter nine, section 9.8.2). However, acknowledging that both groups were presenting perspectives that were included in the analysis, resulted in the researcher considering possible reasons for the different perspectives and looking to the data to provide insights reported above.

12.4.5 Summary of the Tensions Theme Discussion

The theme, the *tensions*, was somewhat different to the concepts identified in the Rycroft-Malone et al. model (2002) (see Figure 12.2). This interpretation of the data were

influenced by the researcher's insider perspective (chapter nine, section 9.8.2). It may be of use because it was how these tensions that arose during the implementation were dealt with that gave insight into what sort of context, culture, leadership, evaluation and facilitation the research site had. The tensions showed the values, beliefs and attitudes that were similar and different amongst the team as well as showing the different needs of different team members related to a guideline (i.e. the needs of experienced staff and of inexperienced staff). The tensions brought out their real beliefs and how they had to work through them to achieve a consensus. Whether the consensus was a result of accommodating individuals' views or did reflect best practice remained a question in some practitioners' minds. Whether this would have been the case had the research evidence been stronger would be interesting to investigate. The tensions and how they were worked through seem to illustrate the dynamism and interplay of the context, the organisation and individuals in the process of developing and implementing a clinical guideline.

12.5 DISCUSSION SUMMARY

It seems that the main reason the extubation guideline did not affect the outcomes in the interrupted time series analysis (chapter eight) was that it did not require clinicians to change their practice, although it may have helped maintain practice through its educative role. The sub category in the product, consensus document, in the theme the *process* points to this conclusion. The reasons for why the guideline ended up as consensus of existing practice may be a result of the way various tensions in the process were resolved. These included a lack of research evidence to support a particular practice; the desire for a flexible guideline and linked to this meeting the differing needs of expert practitioners and novices; resistance to change; differences between the managers and the staff. There is a clear interrelation of the *tensions* with the other themes of *context* and *process*. Sometimes

the *tensions* influenced the *process* and at other times the *process* could be seen to influence the *tensions*. This observation is also relevant to the *context* theme.

The discussion of the results of the qualitative data analysis with the literature on the development and implementation of clinical guidelines and evidence in practice has highlighted some similarities and differences. The *context* clearly had an impact on the development and implementation of the early extubation guideline and the context is considered influential by other authors. More work is needed to understand how contexts affect such practice developments. The concept of context is not yet clear, although some work has been done to help develop this discussion (Rycroft-Malone et al., 2002). The current study highlighted the influence of structural changes (e.g. changing skill mix of staff, case mix changes) on the context, which seems different to other discussions and seems to demonstrate some of the continual movement of healthcare contexts. The role of culture and particularly cultural values was important in this study as in other work (Rycroft-Malone et al., 2002).

The key finding from the *process* theme was that the guideline was a consensus document that did not require a change in practice. This would account for the results of the interrupted time series analysis that the extubation guideline implementation did not affect the outcomes studied. Discussion of the literature explored possible reasons for this. The lack of clear evidence for the effectiveness of different implementation strategies shows that while the nurses used a somewhat emergent, rather than systematically planned implementation process, there is little conclusive evidence to identify how they could improve the process. The lack of research evidence may have contributed to the consensus

however the persistence of the status quo may also have had a strong influence. Both of these discussions have close links to the *tensions* theme.

The negotiation and debate about best practice based on clinical experience was a result of the lack of research evidence in the category identifying best evidence. The debate at the research site accounted for the prominence of the theme *presenting a balanced perspective* from the researcher's reflective diary. The debate resulted in the consensus document.

Resistance to change was linked to this because it seemed clinicians were reluctant to give up their practice preferences without strong evidence that could demonstrate one practice was better than another. This resistance may also be linked to the idea of the persistence of the status quo (National Health Service Centre for Reviews and Dissemination, 1999) or that there is little correlation between the strength of research evidence and its adoption (Dopson et al., 2002). Without investigating a similar guideline implementation where there was a strong research evidence for a change in practice, it is not possible to know for sure what the strongest influences on the production of the extubation guideline were. The general lack of strong research evidence for nursing practice is also a common problem (Thomas et al., 1999a, Thomas et al., 1999b and Thomas, 1999c).

The tension between flexibility and rigidity of the guideline was also an area of debate, that is the need for clinicians to use clinical judgement as well as the need to standardise practice. This tension for the nurses at the research site was also a common concern, particularly in the medical literature. In nursing generally it appears that guidelines are most commonly based on clinical judgement (Thomas et al., 1999a, Thomas et al., 1999b and Thomas, 1999c), possibly because of the general lack of strong research evidence

available to nurses and the associated need to develop the capacity of nurses to effectively appraise and use research evidence in their practice.

The multifaceted nature of implementing evidence, such as a clinical guideline, in health care contexts, that themselves are complex and ever changing, creates a dynamic environment where tensions are inevitable. How these tensions are played out, either through resolution or finding an acceptable way of balancing them, seems to influence the results of particular projects, such as implementing the early extubation guideline. Perhaps how individuals and small groups of clinicians, who are implementing guidelines, respond to the differing tensions is worthy of further investigation. Further research, using both insider and outsider researchers, could attempt to establish whether the tensions in this project can be identified in other similar situations. Such research could help to identify which tensions seem most influential and which responses are the most effective in which circumstances.

CHAPTER THIRTEEN

CONCLUSION AND RECOMMENDATIONS

The question - does standardising nursing practice through the implementation of a clinical guideline for extubating adult cardiac surgical patients improve patient care? - was investigated in this study through a mixed methods approach. Three methods were used: a systematic review of the evidence base for early extubation of adult cardiac surgical patients (Hawkes et al., 2003); an interrupted time series to quantify the impact on professional practice of standardising care through the use of a clinical decision guideline for the early extubation of cardiac surgical patients by nursing staff; and a qualitative study, drawing on applied practitioner ethnography, to investigate the reasons for the results of the interrupted time series and which aimed to identify important factors for the successful implementation of the clinical decision guideline. The systematic review found that, while early extubation reduced intensive care unit (ICU) and hospital length of stay, there were some limitations to the evidence base for the safety of early extubation, the effectiveness of nurse-led early extubation compared with doctor-led early extubation and the decision making processes used for the practice of early extubation. These are discussed further in section 13.1.

The interrupted time series study appeared to be a successful way to measure the impact of standardising care through the use of a clinical guideline on professional practice. The findings indicate that the guideline did not change the outcomes investigated. There were some limitations to this study's use of interrupted time series modelling (see section 13.2.2).

The exploration of the qualitative data resulted in themes that gave insight into the reasons for the lack of change associated with the guideline. The discussion of these themes and comparisons with the associated literature gave some insights into important factors for the successful implementation of clinical guidelines and the limitations of the current knowledge base in this area. Concluding thoughts on the implications of the interrupted time series study and the qualitative study for practice and research are presented in section 13.2.

13.1 SYSTEMATIC REVIEW CONCLUSIONS

The systematic review investigated the evidence base for early extubation (within eight hours of surgery) after cardiac surgery for adult patients. It reviewed not only the evidence for the practice of extubation, but also the effects on patients' recovery and the associated use of resources. The systematic review revealed little evidence about the impact of early extubation on morbidity and mortality nor of the impact of nurse-led early extubation. The review found evidence to support early discharge from intensive care (ICU) and hospital as a result of early extubation after cardiac surgery. The quality of the research in this field needs to be improved.

13.1.1 Implications for Practice

There is no evidence that the rate of death or morbidity is influenced by the timing of extubation after cardiac surgery in adults. This is not the same as evidence of no effect. The protocols, algorithms and individual clinicians' clinical judgement or 'common sense' used to determine when to extubate a patient after cardiac surgery are not supported by the controlled trials included in this review. There is, therefore, no evidence from randomised controlled trials or controlled clinical trials to identify the best practice for an early

extubation guideline. There is no high quality research evidence to identify best practice for a revision of the early extubation guideline at the research site.

13.1.2 Implications for Research

Practice has moved on since the 1990s, when the studies in this review were conducted, and early extubation is now routine practice for most cardiac surgical patients. Future studies should seek to provide stronger evidence for the effects of immediate, or very early extubation compared with early extubation within eight hours of surgery. Studies must be designed using sample sizes determined by their statistical power to detect clinically significant effects in order to improve the quality of research in this area. Best practice in decision making for extubation could be investigated. It is also important to investigate outcomes that are important to patients such as pain control, reducing stress and anxiety and increasing the number of operations performed.

Early extubation is one part of the recovery process for adult cardiac surgical patients. This fast track recovery has many components that effect outcomes. Apart from anaesthetic and surgical techniques and early extubation, fast track cardiac surgery seeks to facilitate a quick postoperative recovery and a short hospital stay, whilst ensuring patients' safety. Postoperative care involves encouraging patients to return to their normal activities, such as eating and drinking, personal hygiene and walking, as soon as possible. Many of these are dependent on recovering mobility, with the help of physiotherapy and good pain control. Early detection and prompt and effective treatment of any problems is also important. The focus of research should not simply be on the extubation times. Future studies should be careful to isolate the aspects of the fast track protocols that they wish to study to avoid

confounding factors that can invalidate the results. Systematic reviews of the different elements of fast track cardiac surgery, such as anaesthetic techniques and the impact of off-pump surgery, would also be valuable for evaluating the current state of research and identifying the direction of future research. Stronger evidence on costs of all these different elements of cardiac surgery could help managers to plan their cardiac surgical services. Studies investigating where patients get held up on their journey through a cardiac surgical department and innovative ways of improving throughput of patients to maximise the number of operations would also be valuable.

The profession of the clinician making the decision to extubate could also be investigated to determine whether this makes a difference to outcomes or the time to extubation. This would provide information for managers as to the best use of resources. For example if nurses or respiratory therapists are shown to be as effective as physicians in this area of decision making, physicians would have more time to concentrate on other areas of practice. However, if immediate extubation is shown to be safe and effective for the majority of patients, the role of nurses, respiratory therapists and doctors in the postoperative period may also change. The skills involved to manage these patients may be different, which may mean additional training for staff. The number of patients who are extubated immediately after surgery that can be safely cared for by one nurse needs to be investigated.

13.2 INTERRUPTED TIME SERIES STUDY AND QUALITATIVE STUDY

The interrupted time series study showed that the implementation of the early extubation guideline at the research site had no effect on the patient outcomes studied. An important reason for this lack of change in practice emerged from the qualitative study. The guideline did not require practitioners to change their practice. The systematic review found no evidence to support the use of a particular practice in extubation to impact on mortality and morbidity of patients that were extubated early. This lack of evidence means that practitioners currently do need to rely on other types of evidence for their guidelines. Experience and expert clinical opinion appears to be the main option until rigorous research is conducted to provide a stronger evidence base.

The early extubation guideline at the research site was based on a local consensus of opinion and it seemed that without rigorous evidence, clinicians could not determine whether one of the two existing ways of practicing was better than the other. After much discussion they decided to include both in their guideline and so no practitioner was required to change their practice. This does not mean that practice was not good or safe. In fact the complication rates for the unit were similar to other published rates (see chapter eleven, section 11.2). The role of the guideline in passing on practice to new members of the nursing staff was clear. Many of the respondents in the qualitative study felt that the guideline was a useful teaching tool. As there was no worsening of the outcomes in the interrupted time series, it may be that the guideline contributed to the maintenance of an already satisfactory standard of practice during a period of change in the skill mix of clinicians, their practice background experience and the case mix of patients.

13.2.1 Implications for Practice

Guidelines need to change practice if they are to improve patient outcomes. However it is possible that standards of practice, and thus patient outcomes, may be maintained in a changing clinical environment through the use of clinical guidelines or protocols.

Improving the evidence base through further research into the areas of practice clinicians' consider important for guideline development would help to improve the quality of guidelines. Guideline development can also help identify areas for further research, particularly when guideline development groups take an approach where the quality of the evidence base for each of their recommendations is make explicit.

The qualitative study identified several aspects of guideline development and implementation that could be improved at the research site. In particular, developing structures to support the process of implementing similar practice developments was identified as important for the future. Another area was improving clarity around roles and responsibilities in the implementation process, as was more training in guideline development and implementation. Other clinicians may find the experiences reported at the research site useful by assessing their value for other settings.

The themes identified in the qualitative study (*context, process and tensions*) demonstrated some of the complexity of implementing guidelines in clinical practice. The interaction of individual skills, preferences and attitudes with those of the team and the organisation are complex. Central to the *context* theme were environmental or resource issues, that is the changing case mix and practice backgrounds and experience of the staff. This focus was somewhat different to other work on implementing evidence in practice. There does not

seem to be a clear understanding of what contextual features impact on the implementation of research evidence in practice or other similar practice developments. Further work to clarify the concept of context and to identifying what, if any, contextual factors are important to research evidence implementation is needed.

The *process* theme offered an explanation for why the implementation of the guideline for early extubation did not affect the patient outcomes in the interrupted time series. This study highlighted some possible causes and effects of a consensus process for developing a clinical guideline. In this case the guideline did not require a change in practice. It would be interesting to investigate a similar implementation process for a guideline that did require a change in practice based on research evidence to assess whether it was the lack of evidence or the consensus process that exerted the most influence on the product (i.e. the guideline).

The theme of *tensions* helped to show that the interactions between individuals, teams and the organisation can cause these tensions and how they are resolved or not impacts on the implementation process and the resulting guideline. The theme of *tensions* and their impact on the implementation process may help clinicians to consciously consider how they want to resolve the tensions created by their practice development projects. It may be that by identifying what the tensions are that are raised by a project may help clinicians work out how to best resolve them. This resolution could be directed to achieve a practice environment and facilitation process, such as those identified in the context and facilitation elements of the Rycroft-Malone et al. model (2002) (see chapter twelve, Figure 12.2), that appears to promote more successful implementation of evidence based practice. This leads back to the central role of facilitation in such practice developments. It may be that

education and training in facilitation skills for project leaders with the appropriate organisational structures and clear managerial support for their role would be a useful way forward in practice.

13.2.2 Implications for Research

High quality rigorous research is needed to identify best practice in extubating adult patients following cardiac surgery and, as practice changes, best practice in caring for patients who are extubated earlier (i.e. within 4 hours), or even immediately, after surgery. This will help improve the evidence base of any future guidelines for the nursing care of adult cardiac surgical patients extubated early.

This study attempted to capture the complexity of guideline implementation and allowed outcome variables to be investigated over time by using statistical modelling in the interrupted time series. The use of an interrupted time series using within person controls seemed to provide useful information on the impact of confounding variables on data collected before and after an intervention in the current study. Further research using interrupted time series to investigate the effect of clinical guidelines on patient outcomes would help establish its value. Some of the limitations of this study (see chapter eleven, section 11.2.3) highlight some areas for development in further research. In particular a longer time series would enable more sophisticated modelling, such as autoregressive moving average (ARMA) or autoregressive integrated moving average (ARIMA) modelling. A longer pre-implementation time series of at least 2 years (i.e. 24 time points) would allow a longer forecast to compare with the actual post-implementation data. A longer time series would also be useful to investigate the impact of longer term trends, such

as the changes in skill mix and case mix highlighted by respondents in the qualitative study (chapter nine, section 9.2.2).

Research, using outcomes relevant to learning practical nursing skills, would contribute to establishing whether the use of the early extubation guideline as an educational tool did contribute to the maintenance of practice. Whether the use of the guideline was sustained because of its educational use is another area that could be investigated.

Further research into the implementation of clinical guidelines is clearly needed. The themes from this study's qualitative data, *context*, *process* and *tensions*, need to be tested. By repeating both the interrupted time series and the qualitative part of this study at different research sites, evidence for the themes' relevance and applicability to a wider range of settings could be generated and the themes themselves could be refined. Having two or more researchers analysing the qualitative data would also improve the credibility or validity of the themes. The themes could also be explored in more depth in a full ethnographic study, using both insider and outsider ethnographers. The themes also contribute to the debate on the concepts involved, such as the context and thus the process of theory building in the area of implementing research in healthcare practice.

However, it can be argued that single site, small-scale research projects can only contribute a limited understanding of such a complex area of healthcare. A number of authors suggest that larger, national and even international research programmes, probably using multiple methods, are needed to improve our knowledge of how research is implemented in practice, through various initiatives including clinical guidelines (Bero et al., 1998, Kitson et al., 1998 and Grimshaw et al., 2004). In ethnography, Hammersley (1992), also suggests that a

programme of research is often necessary to generate enough knowledge to develop theories that can be applied generally rather than to specific research settings.

In an age when quality care and cost effectiveness are important driving forces in health care, future research on clinical guidelines also needs to focus on cost issues. Eccles and Mason (2001) note that guidelines in the United Kingdom have not focused on cost issues, as was the case with the early extubation guideline investigated for the current study. Eccles and Mason (2001) found that there was, as yet, no generally accepted way, either based on theory or practical experience, of successfully including economic factors in clinical guidelines. Grimshaw et al (2004) also found that of the 235 clinical guidelines in their review, only 29% reported costs or cost effectiveness information. The general quality of the methodologies of these studies was poor, making it difficult to make any clear recommendations about the cost effectiveness of different implementation strategies. Economic evaluation of clinical guideline implementation strategies is clearly an area for further research and development. Large programmes of research would be well placed to include such economic evaluations.

13.3 SUMMARY

This study found that the implementation of a clinical guideline for the early extubation of adult cardiac surgical patients did not improve patient outcomes; neither did it make the outcomes worse. The consensus process that developed the guideline may have resulted from a lack of research evidence for best practice and resulted in maintenance of existing practice. This appears to account for the lack of change in patient outcomes. The interrupted time series appears to be a useful way of investigating interventions in healthcare when a randomised controlled trial is not feasible.

More research is needed, not only in clinical practices for which nurses may want to develop clinical guidelines, but also in theory building about implementing research evidence in the complex world of clinical practice. The quality of research, both in the area of postoperative cardiac surgery care and in guideline and other types of research implementation in clinical practice, needs to be significantly improved. Large-scale research programmes that include outcomes that are important to patients, clinicians and service managers could well offer the best way forward, particularly for the implementation of research evidence in clinical practice.

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GLOSSARY

Term	Definition
<	Less than
>	Greater than
≥	Greater than or equal to
Acute cerebral accident or cerebrovascular accident	Stroke
Alveolar – arterial oxygen gradient	The difference in oxygen levels between the blood in the lungs and the blood in the arteries
Anaphylactic shock	Physiological shock caused by an allergic reaction
Anastomoses	A surgical join. E.g. the place where grafts are joined to the existing blood vessels in heart surgery.
Aorta	The main blood vessel coming out of the heart and carrying oxygenated blood.
Aortic aneurysm	Weakness in the wall of the aorta
Aortic cross clamp time	The time the surgeon cuts off the blood supply to the coronary arteries while (s)he joins the grafts to the coronary arteries to bypass the blockages
Arrhythmia	Irregular heart beat (technically absence of heart, but used to indicate irregularity in heart beats)
Arterial blood gas	A measurement of the oxygen and carbon dioxide content of arterial blood.
Arterial grafts	Coronary artery bypass grafts using arteries, rather than veins.
Asthma	A lung disease where the airways constrict causing the patient to wheeze and have difficulty breathing. The constriction in the airways is usually reversible.
Atelectasis	Collapsed areas of lung tissue
Atrial fibrillation	Uncoordinated electrical activity across the upper chambers of the heart (i.e. the atria)
Atrial septal defect (ASD)	Abnormal holes between the atria or upper chambers of the

	heart
AVR	Aortic valve replacement
Base excess	A measure used to assess how alkaline or acid a patients body chemistry is
Blood transfusion	Administration of blood via a drip into a vein
CABG	Coronary artery bypass grafts
Cardiac	To do with the heart
Cardiac arrest	Cessation of the heart's function of pumping blood around the body
Cardiac catheterisation	An investigation to assess the condition of the heart, particularly the blood vessels supplying the heart muscle (coronary arteries).
Cardiac Enzymes	Enzymes that can be detected in the blood and are associated with damage to the heart e.g. CKMB
Cardiac index	A calculated measure of how well the heart is working
Cardiac output	The amount of oxygenated blood ejected from the heart in a minute
Cardiogenic shock	Physiological shock related to the heart
Cardiopulmonary bypass (CPB)	Heart lung bypass
Cardio-respiratory decompensation	Failure of the heart and lungs to respond adequately to changes in the body (i.e. a failure in the normal physiological compensatory mechanism)
Care pathways	Care pathways are tools that provide a route map of care for patients undergoing similar treatments for similar conditions. They usually describe particular interventions and expected outcomes, which would normally occur at specific time points for patients following a particular course of treatment.
Carotid surgery	Surgery on the carotid arteries which are the main arteries supplying the head with blood
Coagulopathy	Disturbance in the blood's normal clotting function

Colloid	Used here as a type of intravenous fluid. Colloids are substances that do not dissolve into a true solution and cannot pass through a semipermeable membrane. This type of intravenous fluid stays in the blood (intravascular space) longer than crystalloid fluids and is therefore useful to increase the circulating volume.
Congestive cardiac failure	Heart failure caused by failure of both sides of the heart (i.e. left and right)
Conventional Extubation	The conventional practice of removing the patient's breathing tube after ending mechanical ventilation before early extubation was tried. Extubation was usually at least 10 hours after surgery and often continued over the night following surgery.
Chronic obstructive pulmonary disease (COPD)	Lung disease where there is usually irreversible airway obstruction (e.g. emphysema)
CPAP – continuous positive airway pressure	Form of non-invasive ventilation
Creatinine	An electrolyte that is found in the body and excreted by the kidneys. Raised blood levels are used to detect problems with the kidneys
Crystalloid	A type of intravenous fluid. Crystalloids are substances that form a true solution and can pass through semipermeable membranes. They contain water and electrolytes. They do not stay in the blood (intravascular space) as long as colloid fluids
CSRA	Cardiac Surgical Recovery Area. An area where cardiac surgical patients go immediately after surgery to recover.
Deep vein thrombosis (DVT)	A clot that develops in a deep vein, causing inflammation and swelling to surrounding tissues.
Diabetes	A condition where the body does not produce enough insulin, which is used to break down sugar for the body to use
Distal	Away from, furthest from
Dysrhythmia	Irregular heart beat
Early extubation	Removing the patient's breathing tube after ending mechanical ventilation, usually within eight hours of surgery

Ejection fraction	The fraction of blood in the left ventricle that is ejected in a heart beat. <30% is considered poor in this study
Electrocardiogram (ECG)	A recording of the electrical activity of the heart
End tidal CO ₂	The amount of carbon dioxide measured at the end of a breath in and out
Endocarditis	Infection of the inside lining of the heart
Endotracheal tube (ET tube)	Breathing tube inserted into patients windpipe and attached by tubing to a ventilator to allow artificial ventilation
Extubation	Removing the patient's breathing tube after ending mechanical ventilation
Fast track pathways or accelerated care pathways	Care pathways that incorporate a accelerated recovery programme for cardiac surgical patients, including early extubation.
Fluid Retention	Fluid retained in the body that would normally be excreted
Fraction of inspired oxygen (fiO ₂)	Amount of oxygen being delivered to a patient expressed as a fraction.
Fresh frozen plasma	Plasma, part of the blood, which can be transfused
Graft	The vein or artery used to bypass the blockage in a coronary artery
Haematocrit	A measurement used to give an indication of the proportion of red blood cells in the blood
Haemostatis	The stable state of the blood and its functions in the body
Haemodynamics	The balance of the bodies circulatory system
Hb	Haemoglobin, the part of the red blood cells that carry oxygen
HDU	High Dependency Unit. A unit where nurse: patient ratios are less than in Intensive Care Units (ICU), but still significantly higher than on a general ward, for example one nurse to every two or three patients
Heart block	A complete block in the pathway electrical activity follows across the heart, in order to regulate the heartbeat.
Hepatic failure	Liver failure

Hypercapnia	High levels of carbon dioxide in the blood
Hypercholesterolaemia	High blood cholesterol levels
Hypoxaemia	Low levels of oxygen in the blood
IABP	Intra-aortic balloon pump. A mechanical device inserted into the aorta and used to give mechanical support to the heart as it pumps
ICU	Intensive care unit
Ileus	Usually, a temporary paralysis in the wave like movements of the muscles in the upper part of the bowel that aids the passage of food
Induction of anaesthesia	Drugs given at the beginning of anaesthesia
Inotropes	Drugs that help support the heart's function, and maintain blood pressure
Intraoperative	During surgery
Intrapulmonary shunt	A measure of how much blood is not being oxygenated in the lungs because of areas of collapsed lung tissue
Intravenous	Into the veins
KPa (kilopascal)	Unit of measurement, used to measure partial pressures of gases (e.g. oxygen) in the blood (used commonly in the UK)
Left ventricular failure (LVF)	A type of heart failure where the left lower chamber (left ventricle) is not functioning well
Lobar collapse	Collapse of a lobar section of the lung
Maintenance of anaesthesia	Drugs given to keep patient anaesthetised during surgery
Mean	Average
Mean inspiratory pressure (MIP)	Mean pressure generated by breathing in (used as a measure of how well a patient is breathing)
Mechanical ventilation or ventilation	Mechanical breathing support
Median	Middle point of a series of numbers

Mesenteric infarction	The mesentery is a membranous tissue with many blood vessels that surrounds the bowel. A infarction is death of tissue beyond a blockage in a blood vessel, this case in the mesentery
Minute ventilation or minute volume	The amount (in litres) of air breathed in and out in one minute
Morbidity	Indicating disease or injury
Morbidity rate	Rate of injury or disease
Mortality	Indicating death
Mortality rate	Death rate
MVR	Mitral valve replacement
Myocardial infarction (MI)	An area of the heart muscle is starved of oxygen because of a blockage in the blood vessel supplying that area. This results in the death of the area of heart muscle
Myocardial ischaemia	The heart muscle is temporarily starved of oxygen because of a reduced supply or increased demand without an associated increase in blood supply
Myomectomy	Removal of a section of myocardium or heart muscle
Myxoma	A tumour of the myocardium (heart muscle)
Negative inspiratory force or pressure	The amount of force or negative pressure generated in the thoracic cavity to cause an in breath

New York Heart Association Functional Class	<p>A grading system of how heart disease is affecting a persons capacity to function. There are 4 classes, I is best function and IV is the worst function:</p> <p>Class I. Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.</p> <p>Class II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.</p> <p>Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.</p> <p>Class IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases</p>
Normothermic	Normal temperature
Oedema	Swelling caused by excess fluid collecting in the tissues of the body
Oncologist	Cancer specialist
Opiates or narcotics	Group of drugs used for anaesthesia and pain control
Oxygen saturation	The amount of oxygen taken up by the haemoglobin (red blood cells) expressed as a percentage
PaCO ₂	Levels of carbon dioxide in the arterial blood (partial pressure of carbon dioxide)
PaO ₂	Levels of oxygen in the arterial blood (partial pressure of oxygen)
Perforated duodenal ulcer	An ulceration in part of the bowel (duodenum) that has caused a hole in the wall of the bowel.
Perforated septum	Perforation of the tissue dividing the right and left side chambers of the heart

Perioperative	During the whole operative period
Peripheral vascular disease (PVD)	A condition where the arteries supplying the peripheral part of the body (e.g. feet and legs) become narrow because of fatty deposits.
Pharmacologic	To do with drugs
Placebo	A substance given like a drug, but that has no active ingredient(s).
Platelets	Platelets are the part of blood which helps with clotting
Pneumonia	Infection in the lungs
Positive end expiratory pressure (PEEP)	The pressure holding the small airways in the lung open at the end of an out breath
Postoperative	After surgery
Premedication	Drugs given prior to surgery
Preoperative	Before surgery
Pulmonary artery wedge pressure (PAWP)	A measurement of the pressure in the main artery from the heart to the lungs
Pulmonary hypertension	High blood pressure in the blood supply to the heart
Pulmonary venous congestion	Congestion in the lungs caused by a backing up of blood in the lungs' blood supply
Pulse oxymeter	A machine that measures the percentage of haemoglobin taking up oxygen (oxygen saturation)
Redo operation	A second or subsequent operation of the same type
Renal insufficiency	Inadequate kidney function
Respiratory	To do with breathing
Respiratory distress	Serious breathing difficulties
Respiratory drive	Mechanism by which the area of the brain responsible for breathing detects the need to regulate pattern and strength of breaths.
Respiratory insufficiency	Inability of person to breath well enough to provide enough oxygen to the body's organs and tissues.

Revascularisation	A variety of procedures used to restore or improve the blood supply to an area of the body, such as the heart muscle
Rheumatic fever	An illness that causes inflammation to joints and heart valves following a bacterial infection.
Sepsis	Infection of the blood
Somnolence	Sleepiness
Spirometry	Some tests to used to determine lung function.
Spontaneous ventilation	Breathing without mechanical assistance
Stenosis	Stiffening, commonly of heart valves
Sternal wound	The surgical wound site where entry is gained for open heart surgery through the sternum or breast bone
T piece	A T shaped attachment to place on the end of an endotracheal tube. An oxygen supply can be attached to it and it is used to assess how well a patient can breath when they are disconnected from a ventilator
Tetralogy of fallot	A congenital abnormality of the heart. It involves pulmonary stenosis (stiffening of the lungs), an opening in the intraventricular septum (hole in the heart between the lower chambers of the heart), malposition of the aorta over the ventricles (lower chambers of the heart) and right ventricular hypertrophy (enlargement of the right lower chamber of the heart)
Tidal volume	The volume of air breathed in and out in one breath (measured in litres)
Torr	A unit of measurement of the partial pressure of gases in the blood (not commonly used nowadays in medical literature)
Transischaemic attack (TIA)	A temporary block in the flow of blood to the brain, causing brain tissue to become starved of oxygen temporarily
Valvotomy	A surgical procedure to help heat valves open that have not been working well
Vasoactive drugs	Drugs that act on the walls of the blood vessels to make them relax or constrict

Venous admixture	This is when venous blood mixes with arterial blood and goes from the right side of the heart to the left side without being oxygenated in the lungs.
Ventilation mode	Different types of ventilation support are provided by mechanical ventilation. These are known as ventilation modes.
Ventricular	Uncoordinated electrical activity across the lower chambers of the heart (i.e. the ventricles)
Ventricular assist device (VAD)	A mechanical device that can be inserted into the heart to help support the function of a failing ventricle. Can be used as an alternative to heart transplant when no donor heart is available
Ventricular septal defect (VSD)	Abnormal holes between ventricles, or lower 2 chambers of the heart
Vital capacity (VC)	The breathing capacity of the lungs measured by the amount of air that can be forcibly breathed out after a full in breath
Weaning	Term used to describe the process of gradually reducing mechanical ventilatory support until a patient is able to breathe unaided

APPENDIX A

OBSERVATIONAL STUDIES OF EARLY EXTUBATION

Table 1a Observational Studies of Early Extubation (Methodology, Sample Size and Inclusion Criteria)

Study	Methodology	Sample size	Inclusion criteria
Klineberg et al., 1977	Observational study. Retrospective review of patient records. 2 study groups: early and conventional	Conventional n = 31 Early n = 72	Early group - consecutive patients over a 4-month period. Conventional group selected from a previous years patients - no details given
Prakash et al., 1977	Observational study of consecutive patients.	142	Men and women age range 14 to 68
Foster et al., 1984	Observational study with historical control group	Early n = 36 Conventional n = 27	Inclusion Criteria: All CABG patients during study period. Exclusion criteria: Severe COPD High risk of post operative complications
Chong et al., 1992	Observational prospective study of consecutive patients in a cardiac surgical recovery area, no control group.	245	Men and women Age range 20 to 77, Patients sent to ITU if – multi-system failure, very poor LV function requiring prolonged IABP, poor respiratory function
Chong et al., 1993	Observational study. Prospective study group and retrospective control to assess the effectiveness of a Cardiac Surgery Recovery Area compared with conventional treatment in an ICU.	Early extubation n = 198 Conventional extubation n = 80	Consecutive patients over a 4 month period (early extubation group) Control group – consecutive patients in 2 months prior to study.
Westaby et al., 1993	Observational study of a prospective consecutive group of adult cardiac surgical patients	Early extubation n = 1000 (719 men, 28 women)	All adult cardiac surgical patients (i.e. non selected)

Study	Methodology	Sample size	Inclusion criteria
Engleman et al., 1994	Observational study of a consecutive series of patients on a fast track protocol, including early extubation, compared with historical control	Early n = 280 Conventional n = 282	Consecutive CABG patients
Massey and Meggit, 1994	Audit consecutive cardiac surgery patients recovered in a CSRA No comparison nor control group	N =100	Age < 70 Normal LV function No serious pre-existing lung disease Normal renal function Normal liver function No previous CVA No MI within last 6 months No drug/alcohol misuse No psychiatric history No current infection Not over 20% of ideal body weight No insulin controlled diabetes No pulmonary hypertension Patient to reach CSRA by 1300 Bypass time < 100min No perioperative critical event Adequate haemostasis PaO ₂ > 12kpa PaCO ₂ <7kpa, Mean arterial blood pressure > 55mmHg

Study	Methodology	Sample size	Inclusion criteria
Coe, 1995	Description of change in practice from conventional to early extubation. Retrospectively collected data presented for 2 time spans during the change period to compare progress.		Young, healthy, first time surgery, no severe lung disease, not renal failure patients included in early extubation protocol
Gross, 1995	Report of implementing an early extubation programme, reporting prospective data on patients selected for the programme	47 patients participated in early extubation programme. This represents 11.2% of the centres cardiac surgery population.	Inclusion criteria: Age < 70 Elective surgery First time cardiac surgery LV ejection fraction > 45 Absence of : Obesity, COPD, renal failure, hepatic failure Arrival in ICU before 4pm Intraoperative exclusion criteria: Prolonged cross-clamp/CPB time Arrhythmia Need for vasoactive drugs to support BP Need for mechanical support (e.g. IABP, VAD) Large volume of crystalloid, colloid or blood products administered
Higgins, 1995	Observational study of before and after early extubation protocol introduced. (Historical control)	Early extubation n = 104 Conventional extubation n = 579	Patients selected on basis of preoperative risk score (low risk)

Study	Methodology	Sample size	Inclusion criteria
Howard, 1995	Description of introduction of a fast track cardiac surgery programme including early extubation and use of a recovery area instead of routine admission to ICU. Paper includes some audit figures	Early extubation n = 409	Fast track selection criteria: parsonnet score <10 Age < 75 Absence of serious lung disease < 30% overweight on standard body mass index if diabetic, well controlled blood sugars, If hypertensive, well controlled LVF > 30% or > 50% if MI within last month No aspirin in preceding 7 days Neurologically intact No other systemic conditions that could compromise rapid recovery
Marquez et al., 1995	Observational study of before and after early extubation protocol introduced. (Historical control)	Early extubation n = 405 Conventional extubation n = 986	All haemodynamically stable CABG patients included
Kozlov et al., 1995	Controlled clinical trial	Early = 49 Conventional = 22	CABG, AVR MVR Tricuspid valve replacement Double valve replacement Maze procedure (Ultrasound destruction of additional conducting channels) CABG + AVR ASD repair

Study	Methodology	Sample size	Inclusion criteria
Edwards and Hess, 1996	Description of transition from conventional extubation to early extubation. Includes report of audit data before (1992) and after (1994) the change.	No information given on numbers of patients on which outcome figures based	Not specified

Study	Methodology	Sample size	Inclusion criteria
Jesurum et al., 1996	Description of implementation of a fast track cardiac surgery programme including early extubation. Observational study data presented from prospective early extubation group and a historical control group	Conventional n= 132 Early n = 153	<p>Early extubation candidates were low risk (<2.5% mortality risk based on risk assessment model based on Bayes Theorum model).</p> <p>Exclusion criteria:</p> <p>Postoperative bleeding requiring > 2 transfusions</p> <p>Intraoperative events associated with adverse outcomes- dysrhythmia, drug reactions, bronchospasm, cardiac events, pulmonary oedema</p> <p>Atrial or ventricular dysrhythmias requiring pharmacologic intervention</p> <p>New ST segment changes on postoperative ECG</p> <p>Surgical re-exploration</p> <p>Stroke or evidence of cerebrovascular event</p> <p>Haemodynamic instability requiring inotrope or IABP</p> <p>Failure to wean and extubate in ≤10 hours</p> <p>Ileus or intolerance of oral intake</p>

Study	Methodology	Sample size	Inclusion criteria
Riddle et al, 1996	Description of implementation of a fast track cardiac surgery programme including early extubation. Observational study data presented from prospective early extubation group and a historical control group	Early n = 303 Conventional n = 312	All patients considered for fast track programme
London et al., 1997	Observational study of a fast track programme including early extubation, using a historical control group and retrospective data collection	Early n = 304 Conventional n = 255	A consecutive cohort of patients having heart surgery requiring CPB were included in the early extubation group. Patients requiring circulatory arrest during surgery were excluded.
Quigley and Reitknecht, 1997	Observational study. Data from consecutive patients collected retrospectively and a historical control group used.	Early n = 266 Conventional n = 266	No preoperative exclusion criteria. Intraoperative exclusion criteria: requirement for inotropes for CPB weaning IABP. Immediate postoperative exclusion criteria: myocardial ischaemia or infarction, dysrhythmias requiring pharmacologic intervention, cardiac index of 2.0L, $\text{fiO}_2 \geq 60$ to maintain $\text{SaO}_2 \geq 90\%$.
Berdar et al., 1998	Pilot study. Prospectively collected data on a fast track (including early extubation) cohort. No control group	100 patients selected for the fast track programme	Inclusion criteria: Elective surgery or urgent/emergent surgery, Uncomplicated previous surgery, Preserved LV function (mean ejection fraction (SD) = 0.56 (0.08)), Informed consent of patient and next of kin

Study	Methodology	Sample size	Inclusion criteria
Gale and Curry, 1999	Description of transition from conventional extubation to early extubation. Includes audit data	672 patients were identified for early extubation out of 1,017 operated on over 19 months.	Not specified how patients identified for early extubation
Hwang et al., 1999	Audit of 6 months of data of early extubation.	110 consecutive patients	Inclusion criteria: Good or moderate LV function, elective surgery, anaesthetised by one of four identified anaesthetist and operated on by one of three identified surgeons
Jacovone et al., 1999	Description of the implementation of a cardiac surgery clinical pathway programme, including early extubation. Retrospective data presented and compared a historical control group.	Early n = 598 Conventional n = 602	None given
Ovrum et al., 2000	Observational study. A review of 10 years data on early extubation	5,658 consecutive patients	All patients. This population excluded patients with severe renal dysfunction, combined carotid and coronary operations, LV aneurysm procedures and emergencies (e.g. failed angioplasties). These types of patient were treated at a neighbouring hospital.
Kaplan et al., 2002	Observational study of early extubation, no comparison group	225 consecutive patients	All cardiac surgery patients, including urgent and emergency cases

Study	Methodology	Sample size	Inclusion criteria
Reis et al., 2002	Observational study using retrospective data. 2 study groups using a historical control group to examine the safety of very early extubation (The conventional group in this study was treated in a similar way to early extubation groups in other studies in this table)	Very early group n = 76 Conventional group n = 188	Exclusion criteria: acute MI < 7 days, reoperation for bleeding, preoperative IABP + vasoactive drugs Missing relevant data

Simeone et al., 2002	Randomised controlled trial to test whether a weaning protocol would reduce intubation times when compared with weaning dependant on physicians clinical judgement only	<p>Protocol group n = 24</p> <p>Control n = 25</p>	<p>Body temperature $>35^{\circ}\text{C} < 38^{\circ}\text{C}$ Stable haemodynamics Urine output $>100\text{ml/hr}$ Normal chest x ray Patient conscious and awake PH 7.3 – 7.5 $\text{PaCO}_2 < 30\text{-}50\text{ mmHg}$ $\text{SatO}_2 > 90\%$ $\text{Hb} > 8\text{ mg/dl}$ Pulse oxymeter oxygenation stable in last 3 hours ($<5\%$ than ABGs) $\text{FiO}_2 < 0.5$ $\text{PaO}_2/\text{fiO}_2 < 200$ Respiratory rate <35 Dynamic compliance staticia $>33\text{ ml/cm H}_2\text{O}$ Vital capacity $>10\text{ml/kg}$ $\text{MIP} \geq 15\text{cm H}_2\text{O}$ $\text{PEEP} < 4\text{cm H}_2\text{O}$ $\text{CPB} < 150\text{min}$ Age $>15\text{ years}$ Exclusion criteria: $\text{FiO}_2 > 0.5$ $\text{PEEP} > 10\text{ cm H}_2\text{O}$ to achieve $\text{O}_2\text{sat} > 90\%$ $\text{PEEP intrinsic} > 10\text{cm H}_2\text{O}$ Excessive respiratory excretions Uncontrolled arrhythmias High inotropic support Bleeding $> 250\text{ ml}$ in first postoperative hour and continuous Contraindications to steroids administration</p>
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Table 1b Observational Studies of Early Extubation (Types of Surgery, Type of Anaesthetic, Intervention)

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Klineberg et al., 1977	CABG	Not given	<p>Conventional group - allowed to wake up passively and usually extubated morning after surgery.</p> <p>Early group - neostigmine and atropine to reverse muscle relaxants and phyostigmine to reverse somnolence once following criteria met: blood loss < 100mls/hr Urine output > 80 ml/hr Cardiovascular system (CVS) - pressures satisfactory with little or no inotropic support and absence of dangerous arrhythmias Respiratory- PaO₂ > or equal to 100 torr with fiO₂ = 0.5 (50% oxygen). Following reversal of anaesthetic if patients then met these criteria: VC at least 10ml/kg, Awake and co-operative, they had a one hour T-piece trial of spontaneous breathing and were extubated if the following criteria met: VC/2 x 30 equal to or > PCO₂x V_E/40^{9,10}</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Prakash et al. 1977	AVR, MVR, AVR and MVR, CABG, MVR and CABG, Resection of ventricular aneurysm, Closure of septum in acute MI, Closure of atrial septum defect (secundum type), correction of tetralogy of fallot, out flow patch for pulmonary stenosis, resection of idiopathic hypertrophic subvalvular aortic stenosis, resection of myxoma	Pre med - papaverin (10-15 mg), haloperidol (2-5 mg), and atropine (0.25 mg) IM. Induction - fentanyl (0.2 - 0.4 mg), pancuronium bromide (6-8 mg), and thiopentone (50 - 150 mg) IV Maintenance - fentanyl, pancuronium bromide, and 60% N ₂ O in O ₂	Patients were selected for extubation as soon as spontaneously breathing. Patients remained ventilated if they met the following criteria: 1. P _{asyst} < 80 torr 2. P _{LA} > 20 torr 3. S _{vo2} < 60% 4. SaO ₂ < 90% 5. PaCO ₂ > 55 torr 6. T _i < 30% 7. Clinical evaluation indicating continued clinical ventilation. If none of the above were observed the patient had a spontaneous ventilation test and remained ventilated if they met the following criteria: 8. Inadequate spontaneous ventilation (unstable ventilation or end-tidal CO ₂ > 55%)

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Foster et al, 1984	CABG	High dose narcotic anaesthesia for both groups	<p>Conventional group extubated under physician direction, mainly on morning after surgery.</p> <p>Early group managed by respiratory therapists following a protocol: Assessed for ability to breath spontaneously 4 hours after surgery. Criteria; Not apprehensive, not diaphoretic Alert and responsive to verbal commands Able to raise arm to command to assess muscle strength Mean arterial BP > 80 mm Hg Left atrial pressure < 20 mm Hg Bleeding < 100ml/hr Temperature 36 –38°C FiO₂ of 0.5 with PaO₂ > 80 torr PEEP < 5cm H₂O No untreated arrhythmia Spontaneous tidal volume ≥5ml/kg Spontaneous vital capacity ≥10ml/kg Respiratory rate ≤30 breaths/min Negative inspiratory force ≥25 cmH₂O If patient maintained these criteria for 30 minutes to 1 hour the physician was contacted for an extubation order.</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Chong et al., 1992	CABG, AVR, MVR, AVR and MVR, CABG and Valves	<p>Premedication - papaveretum (10-20 mg) and hyoscine (0.04 mg) IM</p> <p>Induction: fentanyl (10-15 mcg/kg) and thiopentone (1-3 mg/kg), pancuronium bromide (0.15 mg/kg)</p> <p>Maintenance: nitrous oxide and halothane,</p> <p>During bypass - infusion of propofol (4-6mg/kg/hr) and atracurium (0.5 mg/kg).</p> <p>Reversal: glycopyrate 0.5mg and neostigmine 2.5 mg</p>	<p>Patients allowed to wake straight away. Once spontaneously breathing attached to a Mapleson C circuit with an oxygen flow of 6 L/min.</p> <p>Once ABGs satisfactory ($\text{PaO}_2 > 10\text{kpa}$ $\text{PCO}_2 < 7.5\text{kpa}$ on FiO_2 of 0.5) extubated - nurses specially trained made this decision.</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Chong et al., 1993	CABG, AVR, MVR, AVR & MVR, CABG & valve repair of ASD, aortic root replacement, ventricular aneurysmectomy, tricuspid valve repair, open mitral valveotomy	<p>Both groups premedication – IM papaveretum (10-20 mg), hyoscine (0.2-0.4 mg)</p> <p>Induction – fentanyl (10 –15 mcg/kg), Thiopental (0.5 – 2 mg/kg) or etomidate (0.1 – 0.2 mg/kg) pancuronium bromide (0.1 – 0.15 mg/kg)</p> <p>Maintenance – nitrous oxide and halothane (0.5% to 1%)</p> <p>On CPB: Early extubation group – propofol infusion 4-6 mg/kg/hr. Conventional extubation group – fentanyl (10mcg/kg) and midazolam (5 mg). Atracurium used for additional muscle relaxant if required (10 –25 mg) After CBP halothane in oxygen and air.</p> <p>At end of surgery early extubation group given IV neostigmine (2.5 mg) with glycopyrolate (0.5 mg)</p>	<p>Early extubation group were assessed for extubation as soon as conscious enough to communicate. Extubation criteria: PaO₂ >10kpa PaCO₂ < 8kpa on fiO₂ of .5.</p> <p>Conventional group treatment left to discretion of ICU physician and nursing staff with no emphasis on early extubation.</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Westaby et al., 1993	CABG, AVR, AVR + CABG, MVR, MVR + CABG, double valve replacement + CABG, ASD closure, left ventricular aneurysm resection, CABG + AAA repair, Tricuspid valve replacement	<p>Premedication. – IM papaveretum (10-20 mg), hyoscine (0.4 mg)</p> <p>Induction – fentanyl (10 – 15mcg/kg), Thiopental (1 – 3 mg/kg) or etomidate (0.1 – 0.3 mg/kg) pancuronium bromide (0.15 mg/kg)</p> <p>Maintenance – nitrous oxide and halothane</p> <p>During CPB – IV infusion of propofol (4-6mg/kg/hr) and atracurium (0.5mg/kg).</p> <p>At end of surgery IV neostigmine (0.5 mg) with glycopyrolate (5 mg)</p>	<p>Weaned from ventilatory support as soon as possible.</p> <p>Criteria for extubation:</p> <p>Fully awake and responsive</p> <p>Haemodynamically stable</p> <p>Blood gases PaO₂ >10kpa PCO₂ <7.5kpa on fiO₂ of < 0.5</p> <p>Respiratory rate > 10 and < 30 breaths/min</p> <p>Bleeding < 100ml in preceding 30 min</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Engleman et al., 1994	CABG	<p>Early group:</p> <p>Induction:</p> <p>Sufentanil citrate 1 –2 mcg/kg IV bolus, midazolam 0.05 mg/kg and isoflurane titrated to systolic BP.</p> <p>Maintenance:</p> <p>Sufentanil infusion 0.5 – 1.0 mcg/kg/hr and isoflurane</p> <p>At commencement of CPB:</p> <p>Midazolam 0.025 – 0.05 mg/kg</p> <p>Conventional group:</p> <p>Induction:</p> <p>sufentanil citrate</p> <p>Midazolam 4 – 10 mcg/kg bolus IV</p> <p>Maintenance:</p> <p>midazolam HCl 0.05-0.1 mg/kg IV bolus</p> <p>Sufentanil citrate 50 –100 mcg intermittent IV administration</p> <p>Midazolam infusion up to 0.5 mcg/kg/min.</p> <p>Inhalational anaesthetics rarely used.</p>	

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Massey and Meggit, 1994	CABG, CABG and AVR, CABG and ASD, AVR, ASD	Not given	All patients weaned from ventilatory support as soon as possible once haemodynamically stable and not bleeding excessively. When conscious and able to move all limbs patients connected to O ₂ reservoir circuit. Patients were extubated once arterial blood gases were satisfactory.
Coe, 1995	All cardiac surgery	<p>Premedication. Midazolam and morphine sulfate</p> <p>Induction – midazolam (0.5 – 2 mg), then depending on physiological status –midazolam and/or propofol or midazolam and etomidate and fentanyl titrated to patients response.</p> <p>Maintenance: propofol infusion (25 – 100 mcg/kg/min) and low dose isoflurane.</p> <p>During CPB – propofol infusion and 1-2 mg midazolam bolus.</p> <p>End of bypass: propofol and isoflurane</p>	<p>Weaning criteria:</p> <p>Minimal bleeding</p> <p>Stable haemodynamics</p> <p>No significant arrhythmias</p> <p>Adequate urine output</p> <p>Acceptable oxygen saturation on fiO₂ of 0.5</p> <p>Awake enough to follow commands</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Gross, 1995	CABG Single valve surgery	<p>Premedication: Morphine sulfate IM And diazepam or lorazepam PO</p> <p>Anaesthetic: narcotics, neuromuscular blocking agents, benzodiazepines and inhalational agents as needed. Total doses were approximately fentanyl 1500–3800 mcg, pancuronium or vecuronium 15-30 mg and midazolam 10mg.</p>	<p>Early extubation criteria:</p> <p>No dysrhythmia</p> <p>Haemodynamic stability (cardiac index > 2L/min² per minute)</p> <p>Haemostasis</p> <p>Minimal inotropic support</p> <p>Adequate gaseous exchange</p> <p>Normothermia (Temperature > 37°C)</p>
Higgins, 1995	CABG	Not given, although paper discusses various anaesthetic techniques	<p>Extubation criteria:</p> <p>Awake and responding to command</p> <p>Adequate gag reflex and ability to protect airway</p> <p>Maintain pH > 7.35 on CPAP</p> <p>Haemodynamically stable, no arrhythmias,</p> <p>Bleeding < 10ml/hr for 2 h</p> <p>Core temperature > 36°C, no shivering</p> <p>Well-perfused and adequate urine output</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Howard, 1995	First time CABG, AVR AVR + CABG Simple congenital repair Simple other surgery (e.g. atrial myxoma, pericardial window)	Not given	Once patient is stable, warm and rousable, nurse disconnects patient from ventilator and assesses spontaneous breathing using an rebreathing circuit attached to the ET tube. If breathing well enough to maintain effective gaseous exchange, T-piece with humidified oxygen attached to ET tube. Criteria for extubation: Good respiratory pattern Pain controlled Awake enough to maintain own airway Satisfactory ABGs on $\text{FiO}_2 \leq 50\%$ ($\text{PaO}_2 \geq 10\text{kpa}$ $\text{PCO}_2 \leq 7\text{kpa}$, or as directed by anaesthetist) $\text{SaO}_2 \geq 94\%$ Base excess ≤ 5 and not deteriorating If patient not ready for extubation after 1.5 hours, return to artificial ventilation reconsidered

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Marquez et al., 1995	CABG	<p>Early extubation group: Premedication - Midazolam (30-50 mcg/kg) and morphine (50 – 100 mcg/kg). Induction- Etomidate (0.15-0.3 mg/kg), fentanyl (5-10 mcg/kg), midazolam (0.1-0.2 mg/kg) and isoflurane (0.5-1.5%). Maintenance: pancuronium and isoflurane. (Isoflurane discontinued when haemodynamically unstable and for last 10 min of CPB). Fentanyl and midazolam administered according to anaesthetist preference. Conventional extubation: Premedication – diazepam (70-100 mcg/kg PO) and morphine (50-100 mcg/kg IM) Induction – Fentanyl (25-50 mcg/kg), midazolam (20-50 mcg/kg) and vecuronium (0.1-0.15 mg/kg) Maintenance – same drugs as those used for induction (approximate totals fentanyl 75-100 mcg/kg and midazolam 0.2-0.2 mg/kg)</p>	<p>Patients considered for weaning and extubation at 3-5 hours for early group and at 10 to 12 hours for conventional group. In both groups patients must be haemodynamically stable, minimal bleeding, conscious. Weaning: Over 30 minutes intermittent mandatory ventilation (IMV) rate reduced from 8 to 4 to spontaneous breathing over 30 minutes. Extubation criteria: PaCO₂ < 48mmHg pH > 7.3 Arterial PaO₂ /fiO₂ ratio > 250</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Kozlov et al., 1995	Not clear	<p>Pre med for both groups: promedol 0.3 mg/kg Diazepam 0.2 mg/kg Atropine 0.005 mg/kg</p> <p>Early extubation: Induction: Ketamine 1.6 mg/kg Fentanyl 3.7 mg/kg (41% also had propofol 0.05mg/kg) Pancuronium 0.1 mg/kg</p> <p>Maintenance: Fentanyl and nitrous oxide (40-60%) Propofol in 29% of cases (0.9 – 4.5 mg/kg/hr Enflurane and propofol in 17% of cases.</p> <p>During CPB nitrous oxide discontinued and propofol used 1.4 mg/kg/hr</p> <p>Conventional Extubation: Induction: Fentanyl 15-20mcg/kg Ketamine 0.5- 0.7 mg/kg Pancuronium 0.1-0.15mg/kg.</p> <p>Maintenance (including CPB) fentanyl and pacuronium</p>	<p>Extubation criteria: Haemodynamic stability Absence of coagulopathy (abnormal clotting) Bleeding , 100 ml/hr Satisfactory arterial blood gases on fiO_2 of 0.5, positive end expiratory end pressure of 5cm, minute volume not less than 70% of normal, respiratory rate < 30 breaths/min Arterial pH not less than 7.38 Core temperature 36.5 – 37°C Fully conscious Normal muscular tone</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Edwards and Hess, 1996	Not specified	Anaesthetic techniques not specified, described as a change from heavy to lighter anaesthesia. Use of propofol for sedation and low dose morphine sulphate for pain relief in ICU, instead of morphine, midazolam, diazepam	Once patient awake assessed for weaning and extubation. Criteria: pain and anxiety controlled, bleeding < 100cc/hr, haemodynamically stable, no arrhythmias, core temperature > 36.1°C, FiO ₂ 40% on CPAP, gag reflex present, ability to lift head and follow commands, arterial blood gases checked with anaesthetist for decision to extubate.
Jesurum et al., 1996	CABG	'Traditionally balanced anaesthetic', using morphine, fentanyl, neuromuscular blockade (e.g. pancuronium), benzodiazepines (e.g. midazolam) and inhalational agents. Anaesthetic not modified for early extubation.	Extubation criteria: Normothermic, Neurologically intact, Haemodynamically stable No excessive bleeding
Riddle et al., 1996	CABG Valve CABG + Valve Other cardiac surgery	Early = low-dose short acting narcotics anaesthesia. Conventional = high-dose narcotics anaesthesia No other details given	Patients in the early extubation group were extubated either by 7pm on day of surgery or early morning of postoperative day when adequate staff were available to manage the patient in case of complications following extubation.

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
London et al., 1997	All cardiac surgical patients: CABG, Valves CABG + valve Other cardiac surgery	<p>Anaesthesia not standardised. The early extubation group however received significantly lower doses of fentanyl, sufentanil, midazolam. Fentanyl and midazolam were used in significantly fewer early extubation patients. Sufentanil was used in significantly more early extubation patients. Propofol was often used in place of or in conjunction with lower dose midazolam.</p> <p>Volatile agents were used in significantly more of the early extubation groups anaesthetic. Isoflurane was used for significantly longer times on CPB for the early group.</p>	Once patient was awake, temperature > 36°C, haemodynamically stable on no or minimal inotropic support, no excessive bleeding, ventilatory support reduced rapidly, using ABG results to assess need for support. T-piece trial for 20 –30 minutes before extubation. Readiness for extubation assessed by ABG results.

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Quigley and Reitknecht, 1997	CABG	<p>Early group</p> <p>Premedication: 5-10mg IM morphine and 2 – 4 mg IM midazolam</p> <p>Induction:</p> <p>2 mcg sufentanil and 0.07 mg midazolam and pancuronium 0.15mg/kg all IV.</p> <p>Maintenance:</p> <p>0.2% - 1.5% sevoflurane and oxygen before CPB.</p> <p>During CPB – inhalational agent titrated to BP.</p> <p>Post CPB, sevoflurane titrated to BP</p> <p>Conventional group:</p> <p>Premedication: 70 – 100 mcg diazepam PO, 50 – 100mcg morphine IM.</p> <p>Induction:</p> <p>Sufentanil 4-10 mcg/kg IV bolus and midazolam 0.05- 0.1 g/kg IV.</p> <p>Maintenance: intermittent IV sufentanil bolus of 50 – 100mcg/kg and continuous IV infusion of midazolam \leq0.5 mcg/kg/min. Inhalational agents rarely used.</p>	Early extubation within 6 hours of surgery

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Berdar et al., 1998	CABG AVR MV repair ASD or VSD repair	Short acting drugs used for anaesthesia. Previous midazolam dose halved. Administration of anaesthetic and muscle relaxants via CPB was generally omitted.	Extubation criteria: Patient awake, co-operative, neurological function adequate, Haemodynamically stable without or with low dose inotropes and normal ECG, SaO ₂ > 92%, PaO ₂ > 60 mmHg on FiO ₂ < 0.4 and PEEP 5 cm H ₂ O Respiratory rate 8-15 breaths/min Negative inspiratory pressure > 25 cm H ₂ O, Temperature > 35.5°C
Gale and Curry, 1999	Cardiac surgical patients	Not given	Guidelines developed for nurses to follow. If patient was haemodynamically stable after 1 hour and pain control assessed adequate sedation turned off and ventilation rate gradually reduced. If patient remained stable and SaPaO ₂ > 96%, normal ABGs and had cough reflex a spontaneous breathing trial was commenced using a T piece or pressure support mode of ventilation on FiO ₂ < 50%. Extubation criteria: FiO ₂ < 50% Vital capacity > 10ml/kg Respiration rate > 8 < 30 breaths per min Rapid Shallow Breathing index < 80 ABG = Ph > 7.35; PaCO ₂ < 45 mmHg (< 6 kpa) PaO ₂ > 80mmHg (10 kpa)

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Hwang et al., 1999]	CABG	Anaesthetic dependant on preference of anaesthetist. (Details of each of the 4 anaesthetists preferences are given in the original article)	Extubation criteria: Core temperature > 36.5°C and a core-peripheral temperature gradient of < 2°C Bleeding < 50ml/hr Satisfactory haemodynamic status Patient responsive and able to obey commands Breathing pattern regular at < 20 breaths/min and tidal volume of > 7 ml/kg PaO ₂ > 10 kPa on FiO ₂ < 0.50 and PaCO ₂ < 8 kPa
Jacovone et al., 1999	CABG Valve CABG + valve	Sedative and anaesthetic agents with shorter half lives used for the early extubation group	Core temperature > 36°C and < 39°C MAP ≥65 with or without low –dose inotropic support CI > 2 L (if done) PAWP < 18 Bleeding < 10cc/hr Responsive to command and able to lift arms to command No malignant dysrhythmia PEEP ≤5 cmH ₂ O, pressure support ventilation 5 FiO ₂ ≤0.40 with SaO ₂ ≥90% Minute volume > 6 < 12 litres Forced vital capacity > 10 – 15 ml/kg Respiratory rate ≥6 ≤30 Inspiratory effort/Max pressure > 30 cm H ₂ O PH > 7.3 < 7.5 PaO ₂ > 65 or > 60 if COPD

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Ovrum et al., 2000	CABG	Anaesthesia included a combination of diazepam (0 – 0.2 mg/kg), midazolam (0 – 0.2 mg/kg), low dose fentanyl (4 – 8 mcg/kg), pancuronium, isoflurane and nitrous oxide	Extubation criteria: Patient awake and responsive PaO ₂ > 9 kPa on FiO ₂ < 0.40 and PaCO ₂ < 7 kPa Adequate spontaneous ventilation based on clinical observation Stable circulation with minimal or no inotropic support Bleeding less than 200 ml/hr
Kaplan et al., 2002	CABG on CPB or off pump Valve surgery, replacements and repairs MVR +CABG ASD VSD VSD+AVR VSD + membranous septum aneurysm	Premedication; Midazolam and scopolamine Induction; Fentanyl 10mcg, propofol 2mg/kg, pancuronium 0.1mg/kg Maintenance: sevoflurane, 2.5 mcg/hr fentanyl, and 1.5- 2 mg/hr propofol. Bolus of pancuronium 0.05mg.kg as required	Extubation criteria: Awake, haemodynamically stable Normal body temperature Sufficient oxygenation and respiration Without haemorrhage

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Reis et al., 2002	CABG	<p>Very early group: Premedication: lorazepam Induction: fentanyl (0.0075-0.01 mg/kg) and propofol (0.4-1.0 mg/kg). Maintenance: isoflurane and propofol (2-5mg/hr when on CPB) Postoperative pain control: patient controlled analgesia (PCA) of morphine</p> <p>Conventional group: Premedication: lorazepam and some patients also had morphine and scopolamine Induction: propofol or etomidate Maintenance: Sevoflurane Postoperative pain control: morphine</p>	<p>Extubation criteria: Patient awake, calm and co-operative Bleeding < 75-100ml in last 30 mins Negative inspiratory force > 17-20 cmH₂O Respiratory rate < 30 breaths a min PaCO₂ < 50 mmHg (except COPD) PaO₂ > 70mmHg with FiO₂ <0.5 if possible</p>

Study	Types of surgery included	Type of anaesthetic	Intervention, i.e. what was definition of 'early extubation' and criteria used
Simeone et al, 2002	Elective: CABG, AVR, MVR	<p>Both groups</p> <p>Premedication: night before surgery phenobarbitol (100mg)</p> <p>Day of surgery morphine (0.1 mg/kg) and scopolamine (0.4-0.6 mg/kg).</p> <p>Before induction; metoclopramide (100mg) ranitidine (50mg), methylprednisone (MPS 1g).</p> <p>Induction: Fentanyl(5 mcg/kg) Diazepam (0.3mg.kg) Pancuronium ((0.1 mg/kg).</p> <p>Neourmuscular blockade maintained with atracurium infusion. Bolus doses of fentanyl up to total dose of 10-25 mcg prior to skin incision</p> <p>Maintenance: Oxygen, nitrous oxide and isoflurane</p> <p>During CPB: Thiopental 5mg/kg Propofol infusion (3-5 mg/kg/hr)</p>	<p>Patients in weaning protocol followed an algorithm, gradual reduction of ventilatory support with evaluation every 15 mins maintaining end tidal CO₂ < 5, respiratory rate < 30, SaO₂ >90%. If lowest ventilatory support setting tolerated patient extubated</p> <p>Control group patients were extubated according to physicians judgement</p>

Abbreviations:

$VC/2 \times 30$ equal to or $> PCO_2 \times V_E/40^{9,10}$ = the right side of the equation is the required minute ventilation to maintain a PCO_2 of 40 torr and the left side gives the maximum sustainable minute ventilation. The left side must be equal to or greater than the right side for extubation.

CABG = coronary artery bypass grafts

MVR = Mitral valve replacement

AVR = Aortic valve replacement

AAA = Abdominal aortic aneurysm

ASD = atrial septal defect

VSD = ventricular septal defect

$PaCO_2$ = partial pressure of carbon dioxide in the arterial blood.

PaO_2 = partial pressure of oxygen in the arterial blood.

fiO_2 = fraction of inspired oxygen

CPAP = Continuous positive airway pressure (a mode of ventilatory support)

IMV = intermittent mandatory ventilation (a mode of ventilation where the ventilator allows spontaneous breaths but will deliver a set rate of ventilator breaths per minute)

PEEP = positive end expiratory pressure

PO = per ora (by mouth)

IM = Intra muscular

IV = intravenous

IABP = intra aortic balloon pump

VAD = ventricular assist device

ABG = arterial blood gas

ECG = electrocardiogram (recording of heart rate and rhythm, often used to help diagnose myocardial ischaemia)

Ileus = paralytic ileus (paralysis of the muscles in the ileum (part of the gut) which aid the flow of digested substances through the gut, usually temporary when it occurs following surgery)

Bleeding = blood loss through mediastinal drains

CI = cardiac index

PAWP = pulmonary artery wedge pressure

Table 2: Cardiovascular Outcomes

Study	Outcome measures	Findings/Results	Conclusions
Klineberg et al., 1977	None given		Early extubation is a safe and allows patients to mobilise earlier and go home earlier (with associated cost savings) for the majority of cardiac surgical patients who are not high risk.
Prakash et al., 1977	4 measurements over the 36 hours post-operatively of: Svo ₂ , P _{LA} , and T _i used to assess adequacy of circulation	123 patients were extubated within 3 hours of surgery. 5 of these had to be reintubated: 1 for respiratory distress, 2 for reoperation for postoperative bleeding 1 for an MI 1 who had required IABP preoperatively following a perforated septum following an MI. 19 were not extubated early usually for several reasons, the most frequent were: 14 for a low Svo ₂ , 8 for a high P _{LA} . 16 of these 19 were extubated the following morning and 2 after 36 hours. One died of haemorrhage 7 days post surgery.	The majority of cardiac surgical patients can be safely extubated early after surgery.
Chong et al., 1993	Respiratoy outcomes were main findings discussed. Mortality Hospital length of stay	In hospital mortality not significantly different between the groups (2 in the early extubation groups and 0 in the conventional extubation group) Hospital length of stay was not significantly different between the groups (median of 7 days)	Authors concluded that there were no adverse outcomes that could be attributed directly to early extubation. Only 10% of patients are predicted to be unsuitable for early extubation and treatment in a CRSA rather than and ICU.

Study	Outcome measures	Findings/Results	Conclusions
Westaby et al., 1993	Mortality Need for transfer to ICU for Cardiac Surgery Recovery Area (CRSA)	1.4% mortality : 5 x MI, 4x LVF(all patients were in a poor condition preoperatively), 2 x CVA, 1x mesenteric infarction and septacemia, 1 x aortic dissection, 1x acute malfunction and thrombosis of valve prothesis. 1% of patients transferred to ICU for complications: 3 x COPD with poor respiratory function, 1 x MI requiring prolonged inotropic support, 1 x chest infection, LVF requiring prolonged ventilation and inotropic support	The majority of adult cardiac surgical patients, both elective and emergency, should be considered for early extubation. Pre-operative status does not necessarily predict post operative course. Use of CSRA has reduced costs because beds can be reused once patients are extubated.
Engleman et al., 1994	Use of inotropes New MI Operative mortality Late mortality (1 to 24 months)	Use of inotropes: Early = 42.5%, conventional = 48.8% (p > 0.05) New MI: Early 2.1%, conventional = 1.8% (p> 0.05) Operative mortality; Early = 4%, conventional = 3.7% (p> 0.05) Late mortality (1 to 24 months): Early = 3.6%, conventional = 2% (p > 0.05)	No increased morbidity with fast track demonstrates safety of fast track management of CABG patients.
Massey and Meggit, 1994	Cardiac arrest Anaphylactic shock Atrial fibrillation (AF) Heart block	1 x Cardiac arrest 1 x Anaphylactic shock 4 x AF 2 x Heart block	

Study	Outcome measures	Findings/Results	Conclusions
Gross, 1995	Mortality Cardiac arrest Myocardial ischaemia Atrial dysrhythmia Pericardial effusion Other complications	Mortality = 0 Cardiac arrest = 0 Myocardial ischaemia = 2/47 Atrial dysrhythmia = 4/47 Pericardial effusion = 1/47 Other complications included renal insufficiency, transient ischaemic event, sternal wound infection (no figures given)	Early extubation in the authors selected population appears safe, but further research is needed to validate the practice.
Higgins, 1995]	Postoperative inotropic support Atrial and ventricular arrhythmias MI CVA Mortality Return to theatre to control postoperative bleeding	No significant differences between the 2 groups in any of the outcome measures	Limits of evidence acknowledged, but early extubation appears to be safe. All cardiac surgical patients following this study were considered for early extubation.
Howard, 1995	Mortality Dysrhythmias	Audit data of patients extubated early Mortality = 0.7% Dysrhythmias = 16%	
Marquez et al., 1995	Mortality Clinical risk score used to measure morbidity	Early extubation group mortality = 2.7%, which was comparable with historical data. Clinical risk score comparable between the groups.	High mortality rate could be explained by 75% of the early extubation group having a moderate to high mortality risk score. Early extubation seems safe but authors conclude that further studies examining morbidity and mortality are needed.

Study	Outcome measures	Findings/Results	Conclusions
Kozlov et al., 1995	Requirement for inotropic support on postoperative day 1	Early extubation = 7% Conventional extubation = 41% ($p < 0.05$) No serious complications in either group	
Jesurum et al., 1996	Complications (not specified)	No statistically significant differences in the percentage of complications the early and conventional extubation groups	Small size of study and use of historical control identified as reason for treating the results with caution, although the authors consider their change to a fast track programme has improved outcomes for patients and the hospital.
Riddle et al., 1996	Atrial arrhythmia	% of patients with atrial arrhythmia: Early = 35% Conventional = 35%	

Study	Outcome measures	Findings/Results	Conclusions
Quigley and Reitknecht, 1997	30 day complication rates: Readmission to any hospital Transient strokes Permanent Strokes Mortality	30 day complication rates: Readmission to any hospital: Early = 4% Conventional = 6% (not significant) Transient strokes: Early = 1.5% Conventional = 0.75% (not significant) Permanent Strokes: Early = 0.75% Conventional = 0.75% (not significant) Mortality: Early = 1.88% Conventional = 2.25% (not significant)	
Berdar et al., 1998	Early mortality Late mortality Readmission	Early mortality = 0 Late mortality= 0 Readmission = 2% (1 for AF and 1 for wound healing problem)	Fast track including early extubation did not appear to increase morbidity or mortality and could be applied to about 30% of adult cardiac surgery patients.

Study	Outcome measures	Findings/Results	Conclusions
Ovrum et al., 2000	Resternotomy for bleeding Episodes of AF Postoperative MI IABP Stroke Transient neurologic disturbances In hospital mortality	Resternotomy for bleeding = 2.72% Patients with episodes of AF = 30.63 Postoperative MI = 2.53% IABP = 0.28% Stroke = 0.88% Transient neurologic disturbances = 0.53% In hospital mortality = 0.41%	Early extubation is an important part of changing care to enable quicker discharge from an ICU environment and subsequently from hospital. It appears safe and the morbidity and mortality do not appear to significantly increase.
Kaplan et al., 2002	Early mortality Mortality within 2 months	Early mortality = 1.77% Mortality within 2 months = 0.9%	Early extubation is safe without increasing mortality and morbidity. Analysis for reasons for the failure of the accelerated approach, including early extubation is presented.

Study	Outcome measures	Findings/Results	Conclusions
Reis et al., 2002	<p>Atrial fibrillation</p> <p>Ventricular fibrillation MI CVA</p> <p>30 day mortality</p>	<p>Atrial fibrillation: Very early extubation 22% Conventional extubation 23% (p 0.875)</p> <p>Ventricular fibrillation: Very early extubation 0% Conventional extubation 0.5% (p 0.524)</p> <p>MI: Very early extubation 0% Conventional extubation 0.5% (p 0.524)</p> <p>CVA: Very early extubation 1.3% Conventional extubation 1.1% (p 0.861)</p> <p>30 day mortality Very early extubation 0% Conventional extubation 0%</p>	<p>Very early extubation (extubation within 1 hour) is safe and effective, reducing extubation times with no increase in postoperative complication and is cost effective.</p> <p>The conventional group in this study was treated in a similar way to early extubation groups in other studies in this table.</p>

Abbreviations:

SvO_2 = mixed venous oxygen saturation (provided that SaO_2 and haemoglobin levels are adequate a reduced SvO_2 reflects a low cardiac output in relation to oxygen demand.

P_{LA} = left atrial pressure

T_t = peripheral temperature

P_{syst} = systolic pressure

SaO_2 = oxygen saturation of arterial haemoglobin

$PaCO_2$ = partial pressure of carbon dioxide in the blood.

PaO_2 = partial pressure of oxygen in the blood.

MI = myocardial infarction

CVA = cerebrovascular accident

Inotrope = drug to support the heart to help increase low blood pressure

Arrhythmias = irregular heart rhythms

Table 3: Respiratory and Length of Stay Outcomes

Study	Outcome measures	Findings/Results	Conclusions
Klineberg et al., 1977	<p>% of patients extubated within 5 hours, 10 hours, 15 hours, 20 hours, 25 hours and over 25 hours.</p> <p>Length of ICU stay.</p> <p>Reintubation rates.</p> <p>Length of hospital stay.</p>	<p>Early group: 62.5% were extubated within 5 h, 71% by 10 h, 85% by 20 h and 91% by 25h</p> <p>Conventional group: 3.2% by 5 h, 6.4% by 10 h, 16.2% by 15h, 61.2% by 20h and 77.2% by 25 h.</p> <p>Early group: 46% and 27% stayed 1 or 2 days, respectively in ICU compared to none and 29% in the conventional group. 55% of the conventional group spent 2-3 days in ICU</p> <p>No patients required reintubation.</p> <p>The early group were discharged an average of 4.5 days earlier than the conventional group.</p>	<p>Early extubation is a safe and allows patients to mobilise earlier and go home earlier (with associated cost savings) for the majority of cardiac surgical patients who are not high risk.</p>
Prakash et al., 1977	<p>4 measurements over the 36 hours post-operatively of: PaCO₂ and PaO₂</p> <p>Other outcomes were performed on 27 patients: Pulmonary gas exchange was measured by: V_D/V_T, Qs/Qt, V_A/Qt</p>	<p>PaCO₂ was adequate in the early extubation group, although 17 had PaCO₂ of 50 - 60 torr 1 hour post extubation.</p> <p>PaO₂ was adequate for all patients.</p> <p>Pulmonary gas exchange variables showed no significant changes</p>	<p>Most cardiac surgical patients can be successfully extubated early post-operatively</p>

Study	Outcome measures	Findings/Results	Conclusions
Foster et al., 1984	<p>Time on ventilator</p> <p>Time to extubation</p> <p>Number of ABGs</p> <p>% extubated within 8 hours</p>	<p>Mean (SD) time on ventilator Early = 9.8 (4.4) Conventional = 16.5 (8) ($p < 0.01$)</p> <p>Mean time to extubation Early = 10.8 (4.5) Conventional = 18.2 (8.5) ($p < 0.01$)</p> <p>Mean (SD) number of ABGs Early = 6.6 (2) Conventional 11.4 (5.3) ($p < 0.01$)</p> <p>% extubated within 8 hours Early = 38% Conventional = 4%</p>	<p>Early extubation is safe. Protocol directed extubation can be safely performed by respiratory therapists. Financial analysis not performed but fewer ABGs and less time ventilated should mean reduced costs.</p>
Chong et al. 1993	<p>Duration of ventilation</p> <p>Time to extubation</p> <p>Reintubation rates</p>	<p>Median duration of ventilation - early extubation 1 (0-12) hour, conventional extubation 5 (0 -21) hours ($p < 0.05$)</p> <p>Median (range) time to extubation – early extubation 2 (0-14) hours, conventional extubation 7 (0-22) hours ($p < 0.05$)</p> <p>Reintubation rates: conventional extubation 0/80, early extubation 5/193 (not statistically significant)</p> <p>Comparisons between arterial blood gases before, and at 2 and 4 hours post extubation given, but significance levels not clear</p>	

Study	Outcome measures	Findings/Results	Conclusions
Westaby et al., 1993	% of patients extubated within 3 hours Extubation failure	50% of patients were extubated within 3 hours 1% of patients could not be extubated early	Most cardiac surgical patients can be successfully extubated early post-operatively. High risk preoperative status should not necessarily preclude early extubation

Study	Outcome measures	Findings/Results	Conclusions
Engleman et al., 1994	Extubation time	Median (interquartile range) extubation time: Early = 11.5 hours (9-15.1) Conventional = 17 hours (13.5-22.2)	Most CABG patients can be treated with a fast track programme without increasing the risk of morbidity or mortality. Cost savings are significant with fast track management.
	ICU length of stay	Median (interquartile range) ICU length of stay Early = 2 days (1-2) Conventional = 2 days (2-3) Mean (SD) ICU length of stay: Early = 1.9 (0.1) Conventional = 2.4 (0.1) ($p < 0.001$)	
	Hospital length of stay	Median (interquartile range) hospital length of stay Early = 6 days (4-7) Conventional = 7 days (5-9) Mean (SD) hospital length of stay: Early = 6.8 days (0.3) Conventional 8.3 days (0.3) ($p < 0.001$)	
	% of patients discharged within 3-5 days of operation	Early = 47.5% Conventional = 25.6% ($p < 0.001$)	
	% of patients readmitted within 30 days	% of patients readmitted within 30 days: Early = 8.3 Conventional = 7.1 ($p > 0.05$)	
	Cost savings	Cost savings given as \$2,792,300 for a population of over 700 patients a year	

Study	Outcome measures	Findings/Results	Conclusions
Gross, 1995	<p>Time on ventilator</p> <p>ICU length of stay</p> <p>Hospital length of stay</p> <p>Cost savings</p>	<p>Mean time on ventilator = 7.7 hours compared with an average time of 14–16 hours (data from one month in period before early extubation programme commenced)</p> <p>Mean ICU length of stay = 1 day</p> <p>Mean hospital length of stay = 5.8 days (range 4-16), compared with a mean stay of 7.36 days (data from one month in period before early extubation programme commenced)</p> <p>Cost savings = \$1903 over 10 months</p>	<p>All patients safely and successfully extubated within 8 hours. The practice on this centres selected population appears safe, but the authors suggest more research is needed to validate the practice.</p>

Study	Outcome measures	Findings/Results	Conclusions
Howard, 1995	% of patients admitted to ICU Hospital length of stay	Patients admitted to ICU = 1.5% Median (range) hospital length of stay = 7 (5-40)	Fast track care in a CSRA is a safe and effective way of managing low risk cardiac surgical patients. It means ICU beds are more likely to be available to patients who need them and operations are not dependent on the availability of ICU beds and less likely to be cancelled. Patients benefit from not being in the stressful ICU environment and recover more quickly. Better use of resources means shorter waiting lists. Positive collaboration between the multidisciplinary team has helped the implementation of the programme.
Massey and Meggit, 1994	Ventilation times Recovery unit length of stay Hospital length of stay	Mean ventilation time = 5.57 hours Mean recovery unit length of stay = 6 hours Mean hospital length of stay = 7.15 days	The authors advocate that the use of the CSRA be extended which would benefit patients recovery and reduce the costs of cardiac surgery

Study	Outcome measures	Findings/Results	Conclusions
Coe, 1995	<p data-bbox="368 139 772 198">% of patients extubated in <12 hours</p> <p data-bbox="368 277 772 402">% increase or decrease of patients extubated within 0-3 hours, 3-6 hours, 6-9 hours, 12-24 hours and >24 hours</p> <p data-bbox="368 718 527 744">Reintubation</p>	<p data-bbox="815 139 1257 165">% of patients extubated in <12 hours</p> <p data-bbox="815 172 1044 198">1993 cohort = 49%</p> <p data-bbox="815 205 1108 231">1994-1995 cohort = 70%</p> <p data-bbox="815 277 1481 435">% increase of patients extubated within 0-3 hours between first quarter 1994 and first quarter 1995 = 11%</p> <p data-bbox="815 350 1481 435">% increase of patients extubated within 3-6 hours between first quarter of 1994 and first quarter of 1995 = 10%</p> <p data-bbox="815 448 1481 540">% increase of patients extubated within 6-9 hours between first quarter of 1994 and first quarter of 1995 = 0%</p> <p data-bbox="815 554 1481 613">% decrease of patients extubated 12 - 24 hours between first quarter of 1994 and first quarter of 1995 = 16%</p> <p data-bbox="815 619 1449 679">% decrease of patients extubated > 24 hours between first quarter of 1994 and first quarter of 1995 = 8%</p> <p data-bbox="815 718 1300 744">3 Reintubations in the 1994-1995 cohort</p>	<p data-bbox="1517 139 1885 264">Cost savings and increased patient satisfaction reported by author but no detailed figures given.</p>

Study	Outcome measures	Findings/Results	Conclusions
Higgins, 1995	Reintubation rates Mean time to extubation % of patients extubated within 8 hours ICU length of stay Hospital length of stay % of patients discharged in 5 days	Reintubation rates: none in either group Mean time to extubation: Early extubation = 10.9 hours Conventional extubation = 14.7 (significant) % of patients extubated within 8 hours: Early extubation 34% Conventional extubation 11% (significant) ICU length of stay: Early extubation = 28.1 hours Conventional extubation 29 hours Hospital length of stay: Early extubation = 6.4 days Conventional extubation = 7.8 days (significant) % of patients discharged in 5 days: Early extubation = 32% Conventional extubation = 5%	Early extubation appears to be safe and all patients at the authors institution were subsequently considered for early extubation

Study	Outcome measures	Findings/Results	Conclusions
Marquez, 1995	Ventilation times ICU length of stay Hospital length of stay	<p>Mean ventilation times: Early extubation = 10 hours (± 4.3) Conventional extubation 24 hours (± 8) (significant)</p> <p>ICU length of stay: Early extubation = 24 hours (± 10) Conventional extubation = 48 hours (± 18) (significant)</p> <p>Hospital length of stay Early extubation = 10 days (± 8.8) Conventional extubation = 13 days (± 8.1) (not significant)</p>	
Edwards and Hess, 1996	Mean time to extubation Median extubation time Length of stay for CABG with preoperative cardiac catheterisation Length of stay for CABG without preoperative cardiac catheterisation	<p>Mean time to extubation: Early extubation = 12 hours Conventional extubation = 19 hours</p> <p>Median extubation time = 6 hours</p> <p>Length of stay for CABG with preoperative cardiac catheterisation: Early extubation = 8.2 days Conventional extubation = 12.6 days</p> <p>Length of stay for CABG without preoperative cardiac catheterisation: Early extubation = 6.4 days Conventional extubation 8.3 days Cost savings mentioned but not specified.</p>	

Study	Outcome measures	Findings/Results	Conclusions
Jesurum et al., 1996	<p>Reduction in time to extubation</p> <p>Time to extubation for patients with 0 complications</p> <p>Time to extubation for patients with 1 complication</p> <p>Time to extubation for patients with 2 complications</p> <p>Reintubation</p>	<p>Reduction in average time to extubation for early compared with conventional extubation group= 4 hours</p> <p>Mean time to extubation for patients with 0 complications Early = 6.28 hours Conventional = 10.55 hours ($p \leq 0.05$)</p> <p>Mean time to extubation for patients with 1 complication Early = 8.21 hours Conventional = 12.10 hours ($p \leq 0.05$)</p> <p>Mean time to extubation for patients with 2 complications Early = 19.10 hours Conventional = 34 hours ($p \leq 0.05$)</p> <p>Reintubation rate: Early = 0 Conventional = 0</p>	<p>Small size of study and use of historical control identified as reason for treating the results with caution, although the authors consider their change to a fast track programme has improved outcomes for patients and the hospital.</p>

Study	Outcome measures	Findings/Results	Conclusions
Riddle et al., 1996	Ventilation time	Mean ventilation time: Early = 17 hours Conventional = 2.2 days	The implementation of the fast track programme has helped improve care, including reducing costs and length of stay
	ICU length of stay	Mean (SD) ICU length of stay: Early = 1.7 days (1.15) Conventional = 3.3 days (3.75) (p < 0.0001)	
	Hospital length of stay	Mean (SD) hospital length of stay: Early = 5.9 days (4.67) Conventional = 9.3 (7.41) (p < 0.001)	
	Infection: Ventilator related pneumonia	Infection: Ventilator related pneumonia: Early = 2.6% Conventional = 5.1% (not significant)	
	Sternal wound infection	Sternal wound infection: Early = 0 .33% Conventional = 0.96% (not significant)	
	Donor wound infection	Donor wound infection: Early = 0.66% Conventional = 0.96% (not significant)	
	Costs	Cost comparisons presented although no detailed calculations presented: Mean (SD) cost of all cardiac surgery: Early = \$24, 722 (\$10,057) Conventional = \$27,635 (\$15,149)	

Study	Outcome measures	Findings/Results	Conclusions
London et al., 1997	<p>Duration of intubation</p> <p>Reintubation rates</p> <p>ICU length of stay</p> <p>Hospital length of stay</p> <p>Median postoperative day of discharge</p> <p>Post operative complications</p>	<p>Mean (SD) duration of intubation: Early = 17.3 hours (28.6) Conventional = 27.8 hours (28.3) ($p < 0.001$)</p> <p>Median duration of intubation Early = 10.2 hours Conventional = 19.2 hours</p> <p>Reintubation rates: Early = 5% Conventional = 6.3% (not significant)</p> <p>Mean (SD) ICU length of stay: Early = 91 (145) hours Conventional = 144 (189) hours ($p < 0.001$)</p> <p>Median ICU length of stay: Early = 49 hours Conventional = 96 hours</p> <p>Mean (SD) hospital length of stay: Early = 228 (252) hours Conventional = 291 (213) hours ($p < 0.001$)</p> <p>Median hospital length of stay: Early = 167 hours Conventional = 222 hours</p> <p>Early = day 7 Conventional = day 10 ($p < 0.001$)</p> <p>There were no significant differences in the frequency of a major postoperative complications, adult respiratory distress syndrome (ARDS)</p> <p>There were no significant differences in the frequency of minor postoperative complications (prolonged use of oxygen, pneumonia requiring antibiotics, discharge home on nasal oxygen operations)</p>	<p>This study indicates (within the limitations of the design) that fast track management, including early extubation, does not appear to increase morbidity or mortality. It appears to reduce ventilation time, ICU and hospital length of stay and results in cost savings.</p>

Study	Outcome measures	Findings/Results	Conclusions
Quigley and Reitknecht, 1997	Time to extubation	Mean (SD) time to extubation: Early = 10.16 hours (10.8) Conventional = 38.4 hours (6.38) ($p < 0.0001$)	Introduction of fast track programme has not compromised patient care or outcomes and has saved the hospital a significant amount of money.
	% of patients extubated at 24 hours	% of patients extubated at 24 hours: Early = 95% Conventional = 0% ($p < 0.0001$)	
	ICU length of stay	Mean (SD) ICU length of stay: Early = 1.7 days (0.8) Conventional = 2.6 days (0.6) (< 0.001)	
	Hospital length of stay	Hospital length of stay: Early = 6.4 days (1.2) Conventional 7.5 days (0.9) ($p < 0.001$)	
	Sternal wound infection	% of patients with sternal wound infection at 30 days postoperatively: Early = 1.88% Conventional = 1.12% (not significant)	
	ICU cost savings	ICU cost savings = \$172,900 for the 266 early extubation group (fast track management)	

Study	Outcome measures	Findings/Results	Conclusions
Berdar et al., 1998	Intubation time ICU length of stay Hospital length of stay	Mean (SD) intubation time: Early = 4.5 (3) hours Mean (SD) ICU length of stay: Early = 16 (3) hours Mean (SD) hospital length of stay: Early = 4.9 (2.1) days	Fast track programmes, including early extubation, for selected patients seem to be safe and can reduce costs

Study	Outcome measures	Findings/Results	Conclusions
Jacovone et al., 1999	Time on ventilator	Mean (SD) time on ventilator: Early = 8 (1.4) hours Conventional = 17 (4.8) hours (no statistical significance reported)	The programme was viewed as successful and further improvements in ventilation time are noted. The multidisciplinary team continues to work to identify areas for improvement. The role of the Clinical Nurse Specialist is highlighted in the article, as a co-ordinator for the programme implementation.
	Prolonged ventilation	Prolonged ventilation (>24 hours): Early = 9.03% Conventional = 10.3% (no statistical significance reported)	
	Pneumonia	Pneumonia: Early = 1.67% Conventional = 2.49% (p = 0.05)	
	Hospital length of stay	Mean hospital length of stay for valve surgery: Early = 7 days Conventional = 8 days Hospital length of stay for patients having other types of cardiac surgery was unchanged.	
	Cost savings	Savings of \$201,000 per year for the valve surgery group of patients was reported.	

Study	Outcome measures	Findings/Results	Conclusions
Hwang et al., 1999	<p>Time to extubation for the four (A, B, C, D) different anaesthetic regimens</p> <p>% of patients extubated within 4 hours</p> <p>Reintubation</p>	<p>Median (range) time to extubation for the four (A, B, C, D) different anaesthetic regimens</p> <p>A = 8.46 (0 – 23) hours</p> <p>B = 3.54 (0.17 – 20) hours</p> <p>C = 4.38 (1.33 – 20.33) hours</p> <p>D = 8.67 (0.67 – 20.17) hours ($p < 0.05$)</p> <p>% of patients extubated within 4 hours = 45.5%</p> <p>Reintubation rate = 0</p>	<p>Education was a key factor in the successful implementation of early extubation. This happened over a period of time and sub group analysis of the audit data showed that extubation times were continuing to decrease. Close co-operation between all those caring for these patients was necessary.</p> <p>Discharge from ICU was not shorter for this institution due to restricted bed availability in the ward and discharge was dependent on surgeon preference. These areas and the development of a fast track protocol were identified as areas for future development.</p>

Study	Outcome measures	Findings/Results	Conclusions
Gale and Curry, 1999	<p>% extubated within 8 hours</p> <p>% successfully weaned and extubated by nurses</p> <p>Reintubation rate</p> <p>% of patients identified for early extubation that were extubated by 16 hours</p>	<p>72% extubated within 8 hours</p> <p>94%% successfully weaned and extubated by nurses</p> <p>0.2% reintubation rate</p> <p>94% of patients identified for early extubation that were extubated by 16 hours</p>	The development of the guideline for early extubation provided development opportunities for nurses, promoted collaboration of multiprofessional team and audit results indicate that guideline or protocol driven weaning and extubation criteria are more effective and efficient than clinician directed weaning and extubation.
Ovrum et al, 2000	<p>Extubated in theatre</p> <p>Extubated: Within 1 hour Within 2 hours Within 3 hours Within 4 hours Within 5 hours</p> <p>Extubation time</p> <p>Reintubation</p> <p>Duration of reintubation</p>	<p>Extubated in theatre = 0.9%</p> <p>Extubated: Within 1 hour = 30.8% Within 2 hours = 75.1% Within 3 hours = 92.7% Within 4 hours = 98% Within 5 hours = 99.3%</p> <p>Median (range) extubation time = 1.5 (0 – 320) hours</p> <p>Reintubation = 1.1%</p> <p>Duration of reintubation = 24 (1 – 420) hours</p>	Fast track protocols including early extubation appear to reduce costs without increasing morbidity and mortality. However reduced ICU and hospital length of stay are used as proxy outcome measures for improved outcome. To make a more accurate evaluation or the patients' medical progress, studies of daily detailed status, including physical status, are needed.

Study	Outcome measures	Findings/Results	Conclusions
Kaplan et al., 2002	Extubation times Reintubation ICU length of stay Hospital length of stay	Mean (SD) extubation time = 3.97 (1.59) hours Reintubation = 2/225 (0.9%) Mean (SD) ICU length of stay 20.93 (2.44) Mean (SD) hospital length of stay 4.24 (0.75) days	Early extubation is safe without increasing mortality and morbidity. The accelerated recovery approach (including early extubation) was used for 75.5% of patients. Analysis of reasons for patients not following the accelerated approach is presented.
Reis et al., 2002	Ventilation times % of patients extubated immediately on arrival in ICU Reintubation Hospital length of stay	Ventilation times: Mean very early extubation = 0.5 (+ or - 0.9) hours Mean conventional extubation = 6.8 (+ or - 6.9) hours (p<0.001) Median (range) very early extubation = 0 (0-4) hours Median (range) conventional extubation = 4 (0-64) hours (p<0.001) % of patients extubated immediately after surgery Very early extubation = 42% Conventional extubation = 2% (p< 0.001) Reintubation Very early extubation 1.3% Conventional extubation 0.5% (p 0.506) Mean (SD) Hospital length of stay: Very early extubation = 6.9 (2.3) Conventional extubation = 7.5 (7.5) (p 0.906)	Very early extubation appears safe, reducing ventilation times without increasing the risk of morbidity or mortality. The conventional group in this study was treated in a similar way to early extubation groups in other studies in this table.

Study	Outcome measures	Findings/Results	Conclusions
Simeone et al., 2002	Ventilation time ICU length of stay	Mean (SD) ventilation time: Weaning protocol group = 6.5 (3.8) Physician directed group = 8.6 (3.5) (p = 0.05) Mean (SD) ICU length of stay: Weaning protocol group = 29 (15.8) Physician directed group = 46.1 (33.9)	The use of a weaning protocol significantly reduced ventilation times and ICU stay without increased morbidity. The samples in this study are very small and the power of the sample to detect clinically significant differences between groups is not reported. The results should be treated with caution.

APPENDIX B

DATA COLLECTION TOOLS

Systematic Review
DATA EXTRACTION FORM

Study ID:

Authors:

Medline Journal ID:

Year of Publication:

Language:

Type of Study:
randomised

RCT ____

CCT ____

Non-

Comments on Study Design:

QUALITY OF CONCEALMENT OF ALLOCATION POINTS

Allocation was not concealed (e.g. quasi-randomisation)	0
Allocation concealment was not stated or was unclear	1
Disclosure of allocation was a possibility	2
Allocation was concealed (e.g. numbered, sealed opaque envelopes drawn NON consecutively)	3
Inclusion and exclusion criteria were not clearly defined in the text	0
Inclusion and exclusion criteria were clearly defined in the text	1
Outcomes of patients who withdrew or were excluded after allocation were NEITHER detailed separately NOR included in an intention to treat	0
Outcomes of patients who withdrew or were excluded after allocation were EITHER detailed separately OR included in an intention to treat analysis OR the text stated there were no withdrawals	1
Treatment and control groups were NOT adequately described at entry	0
Treatment and control groups were adequately described at entry A minimum of 4 admission details were described (e.g. age, sex, mobility, type of surgery, ASA grade, function score, mental test score)	1
The text stated that the care programmes other than trial options were NOT identical	0
The text stated that the care programmes other than trial options were identical	1
Outcome measures were NOT clearly defined in the text	0
Outcome measures were clearly defined in the text	1
Outcome assessors were NOT blind to the allocation of patients	0
Outcome assessors were blind to the allocation of patients	1
The timing of the measurement of the outcomes was NOT appropriate	0
The timing of the measurement of the outcomes was appropriate	1

METHODS:

Study population selected to be: high risk	Yes	No	Unclear
Low/moderate risk	Yes	No	Unclear
Not selected (i.e. all)	Yes	No	Unclear

Subject -Blinded	Yes	No	Unclear
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Physician - Blinded	Yes	No	Unclear
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Outcome Assessor –Blinded	Yes	No	Unclear
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PARTICIPANTS:

Number of eligible participants:		Number enrolled in study:	
Number of participants at in hospital data collection point:	Number of participants at 30 day follow up:	Number of participants at 6 month/1year follow up:	
Health Care Professional making decision to extubate Doctor Other HCP Unclear			

Sample Demographics

INTERVENTION:	Age (mean, SD)	Men (n, %) Women (n, %)	Left Ventricular function (mean (EF)+SD)	Pre-op IABP/ inotropes/both (n, %)
Treatment Group 1: Early extubation				
Treatment Group 2: Conventional extubation				

Sample Demographics

INTERVENTION:	Diabetic (n, %)	Renal impairment (n, %)	3 vessel disease (n, %)	2 vessel disease (n, %)	1 vessel disease(n, %)
Treatment Group 1: Early extubation					
Treatment Group 2: Conventional extubation					438

INTERVENTION:	Cases: elective/ Emergency/both (n,% of each/all)	redo surgery (n, %)	Anaesthetic agents	Doses	Route (IV, oral etc.)
Treatment Group 1: Early extubation					
Treatment Group 2: Conventional extubation					

INTERVENTION:	Types of Surgery Included (CABG, Valve, CABG+valve Aortic surgery)	Cardiopulmonary bypass time (mean (min.) SD)	cross clamp time (mean (min.) SD)	No. of grafts (mean, SD (min.))
Treatment Group 1:				
Treatment Group 2:				

INTERVENTION:	On or off cardiopul- monary bypass/both (n, % for each)	Core temp. at end of surgery (mean, SD)	Intra operative IABP/inotrope(s) (n, %)
Treatment Group 1: Early extubation			
Treatment Group 2: Conventional extubation			

INTERVENTION:	Extubation criteria (list)
Treatment Group 1: Early extubation	
Treatment Group 2: Conventional extubation	

COMMENTS ON INTERVENTION:

OUTCOMES:	Extubated < 4 hours (n, %)	Extubated 4 –8 hours (n, %)	Extubated > 8 hours (n, %)
Treatment Group 1:			
Treatment Group 2:			

OUTCOMES:	Mortality – in ICU (n, %)	Mortality – 30 day (n, %)	Mortality–Late (31 days up to 1 year) (n, %)
Treatment Group 1:			
Treatment Group 2:			

OUTCOMES:	Morbidity – Ischaemia (n, %)	Morbidity – reintubation @24 h (n, %)	Morbidity reintubation after 24 h (n, % and list reasons for reintubation)
Treatment Group 1:			
Treatment Group 2:			

OUTCOMES:	Morbidity – atelectasis 24 h (n, %)	Morbidity atelectasis 48h (n, %)	Morbidity atelectasis 72h (n, %)
Treatment Group 1:			
Treatment Group 2:			

OUTCOMES:

	Morbidity – PaO ₂ and PCO ₂ ≤30 mins (mean and SD for both)	Morbidity – PaO ₂ and PCO ₂ at c. 4 h (mean and SD for both)	Morbidity – (Qs/Qt) ≤30 mins (mean, SD)	Morbidity (Qs/Qt) at c. 4 h (mean, SD)	Morbidity (A/a grad.) ≤30 mins (mean, SD)
Treatment Group 1:					
Treatment Group 2:					

OUTCOMES:

	Morbidity A/a grad. At c.4 h (mean, SD)	ICU length of stay (mean, SD)	Hospital length of stay (mean, SD)	Other outcomes (specify) (mean, SD or n, % as appropriate)
Treatment Group 1:				
Treatment Group 2:				

CHANGES IN PROTOCOL:

CONTACT WITH AUTHOR:

OTHER COMMENTS ON THIS STUDY:

INTERRUPTED TIME SERIES

PATIENT DATA COLLECTION SHEET INCLUSION CRITERIA

[illegible]

Age:

- Previous cardiac history codes:**
- 1 MI = previous myocardial infarction
 - 2 UA = unstable angina
 - 3 SA = stable angina
 - 4 H = hypertension (*> 140/90 or written as diagnosis*)
 - 5 AF = usually in atrial fibrillation
 - 6 LTD = history of life threatening dysrhythmias (VT, VF. CA = previous cardiac arrest)

- Previous respiratory history codes:**
- 1 A = asthma, with need for bronchodilators/steroids
 - 2 COPD = chronic pulmonary obstructive disease, with need for bronchodilator therapy
 - 3 S = smoking with sub categories: Y = currently a smoker, N= never smoked, P = previously a smoker but given up smoking for more than 6 months
 - 4 P = known pulmonary hypertension
 - 5 O = other serious respiratory disease (*note disease for post coding*)

- Other relevant medical history codes:**
- 1 R = abnormal renal function, raised pre-operative creatinine level ≥ 150 (*check what measured in*)
 - 2 D = Diabetic, Y or N
 - 3 O = other (*note disease for post coding*)

Left ventricular function from cardiac catheter result codes:

- 1 P = poor ejection fraction of $<20\%$
- 2 M = moderate, ejection fraction of $20-40\%$
- 3 G = good, ejection fraction of $>40\%$.

DATA COLLECTION SHEET FOR EARLY EXTUBATION OUTCOMES

[illegible]

Respiratory reasons for reintubation codes:

- 1 CI = Respiratory failure caused by chest infection/ sputum retention/consolidation
- 2 PO = pulmonary oedema
- 3 BC = basal collapse
- 4 O = other note causes for post coding.

Cardiac reasons for reintubation:

- 1 B = bleeding requiring reintubation e.g. for re-opening
- 2 CT = cardiac tamponade
- 3 LTD = life threatening dysrhythmias (VT, VF) causing loss of output and requiring intubation

Surgeon

- 1 (Initials used)
- 2 (Initials used) 3 RP
- 4 (Initials used)
- 5 (Initials used)
- 6 Registrar, under consultants supervision

**PATIENT DATA COLLECTION SHEET FOR FLUIDS AND
ARTERIAL BLOOD GASES**

Patient ID	Colloid fluid balance at 0800 on post operative day 1 in mls	Was surgery on or off bypass 1=on bypass, 2 = off bypass	Number of Arterial Blood Gases taken from admission to unit to 0800 on post operative day 1	Comments

QUALITATIVE STUDY
INTERVIEW SCHEDULE
STANDARDISING NURSE LED EXTUBATION OF CARDIAC SURGICAL
PATIENTS

Semi-structured interviews were conducted with staff and managers involved in the development and implementation of the protocol.

Interviewees:

- Anaesthetist - cardiac surgery
- Practice Development Nurse
- Unit Nurse Manager
- Members of the protocol development group
- Nursing staff who use the protocol, with a range of experience in cardiac intensive care

Topics covered in the interviews with staff involved in the implementation of this protocol:

- Objectives in developing and implementing the protocol
- The interviewee's role in developing and/or implementing the protocol
- What was involved in developing/implementing the protocol
- What went well
- What was difficult and how was this tackled
- Anything the interviewee has learnt that would influence developing/implementing protocols in the future
- Views of the effectiveness of the protocol and its implementation, and how well the objectives have been met
- Views of the staff using the protocol on how easy it is to use and how helpful they have found it.
- Views on the researcher's role in and affect on the implementation of the protocol

Managers who were not directly involved in the implementation of this particular protocol will be asked more generally about the organisation's attitudes to, policies on clinical protocols, their role regarding implementing protocols.

APPENDIX C

SEARCH STRATEGIES FOR THE SYSTEMATIC REVIEW

Search Strategy for MEDLINE from January 1966 to June 2003

- #1 explode "Cardiac-Surgical-Procedures"/ all subheadings**
- #2 "Thoracic-Surgery"/ all subheadings**
- #3 heart**
- #4 surgery**
- #5 heart surgery**
- #6 cardiac**
- #7 surgery**
- #8 cardiac surgery**
- #9 explode "Coronary-Artery-Bypass"/ all subheadings**
- #10 #1 or #2 or #5 or #8 or #9**
- #11 early**
- #12 extubation**
- #13 early near extubation**
- #14 removal**
- #15 endotracheal**
- #16 removal near endotracheal**
- #17 "Anesthesia-Recovery-Period" in MIME,MJME**
- #18 fast**
- #19 track**
- #20 fast track**
- #21 #13 or #16 or #17 or #20**
- #22 #10 and #21**
- #23 RANDOMIZED-CONTROLLED-TRIAL in PT**
- #24 CONTROLLED-CLINICAL-TRIAL in PT**

#25 RANDOMIZED-CONTROLLED-TRIALS
 #26 RANDOM-ALLOCATION
 #27 DOUBLE-BLIND-METHOD
 #28 SINGLE-BLIND-METHOD
 #29 #23 or #24 or #25 or #26 or #27 or #28
 #30 TG=ANIMAL
 #31 TG=HUMAN
 #32 TG=ANIMAL
 #33 (TG=ANIMAL) not ((TG=HUMAN) and (TG=ANIMAL))
 #34 #29 not #33
 #35 CLINICAL-TRIAL in PT
 #36 explode CLINICAL-TRIALS/ all subheadings
 #37 clin*
 #38 trial*
 #39 (clin* near trial*) in TI
 #40 clin*
 #41 trial*
 #42 (clin* near trial*) in AB
 #43 singl*
 #44 double*
 #45 trebl*
 #46 tripl*
 #47 blind*
 #48 mask*
 #49 (singl* or double* or trebl* or tripl*) near (blind* or mask*)

#50 (#49 in TI) or (#49 in AB)

#51 PLACEBOS

#52 placebo*

#53 placebo* in TI

#54 placebo*

#55 placebo* in AB

#56 random*

#57 random* in TI

#58 random*

#59 random* in AB

#60 RESEARCH-DESIGN

#61 #35 or #36 or #39 or #42 or #50 or #51 or #52 or #53 or #54 or #55 or #57 or #59 or
#60

#62 TG=ANIMAL

#63 TG=HUMAN

#64 TG=ANIMAL

#65 (TG=ANIMAL) not ((TG=HUMAN) and (TG=ANIMAL))

#66 #61 not #65

#67 #66 not #34

#68 TG=COMPARATIVE-STUDY

#69 explode EVALUATION-STUDIES/ all subheadings

#70 FOLLOW-UP-STUDIES

#71 PROSPECTIVE-STUDIES

#72 control*

#73 prospectiv*

#74 volunteer*

#75 control* or prospectiv* or volunteer*

#76 (#75 in TI) or (#75 in AB)

#77 #68 or #69 or #70 or #71 or #76

#78 TG=ANIMAL

#79 TG=HUMAN

#80 TG=ANIMAL

#81 (TG=ANIMAL) not ((TG=HUMAN) and (TG=ANIMAL))

#82 #77 not #81

#83 #82 not (#34 or #67)

#84 #34 or #67 or #83

#85 #22 and #84

#86 explode "Child"/ all subheadings

#87 explode "Adolescence"/ all subheadings

#88 #86 or #87

#89 explode "Adult"/ all subheadings

#90 explode "Aged"/ all subheadings

#91 #89 or #90

#92 #88 not (#88 or #91)

#93 #85 not #92

Strategy for EMBASE January 1980 to June 2003

#1 explode "comparative-study"/ all subheadings

#2 explode "controlled-study"/ all subheadings

#3 explode "clinical-trial"/ all subheadings

#4 explode "clinical-study"/ all subheadings
 #5 "crossover-procedure"/ all subheadings
 #6 "double-blind-procedure"/ all subheadings
 #7 "single-blind-procedure"/ all subheadings
 #8 random*
 #9 single?blind*
 #10 double?blind*
 #11 triple?blind*
 #12 treb?blind*
 #13 control*
 #14 trial
 #15 (random* or single?blind* or double?blind* or triple?blind* or treb?blind* or control*) near trial
 #16 "placebo"/ all subheadings
 #17 explode "evidence-based-medicine"/ all subheadings
 #18 explode "human"/ all subheadings
 #19 "human-experiment"/ all subheadings
 #20 #18 or #19
 #21 explode "animal"/ all subheadings
 #22 explode "animal-experiment"/ all subheadings
 #23 #21 or #22
 #24 #23 not (#23 and #20)
 #25 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #15 or #16 or #17
 #26 #25 not #24
 #27 explode "heart-surgery"/ all subheadings

#28 explode "coronary-artery-surgery"/ all subheadings

#29 explode "heart-valve-surgery"/ all subheadings

#30 heart

#31 surgery

#32 heart surgery

#33 cardiac

#34 surgery

#35 cardiac surgery

#36 #27 or #28 or #29 or #32 or #35

#37 early

#38 extubation

#39 early near extubation

#40 removal

#41 endotracheal

#42 tube

#43 removal near endotracheal tube

#44 "anesthetic-recovery"/ all subheadings

#45 fast

#46 track

#47 fast track

#48 #39 or #43 or #44 or #47

#49 #36 and #48

#50 #26 and #49

#51 explode "child"/ all subheadings

#52 explode "childhood"/ all subheadings

#53 explode "adolescent"/ all subheadings

#54 #51 or #52 or #53

#55 "adult"/ all subheadings

#56 "adulthood"/ all subheadings

#57 "aged"/ all subheadings

#58 #55 or #56 or #57

#59 #54 not (#54 and #58)

#60 #50 not #59

Strategy for CINAHL January 1982 to December 2002

#1 "Pilot-Studies"/ all topical subheadings / all age subheadings

#2 "Reproducibility-of-Results"/ all topical subheadings / all age subheadings

#3 explode "Reliability-and-Validity"/ all topical subheadings / all age subheadings

#4 explode "Clinical-Research"/ all topical subheadings / all age subheadings #5 explode

"Research-Methodology"/ all topical subheadings / all age subheadings

#6 "Meta-Analysis"/ all topical subheadings / all age subheadings

#7 "Crossover-Design"/ all topical subheadings / all age subheadings

#8 "Patient-Selection"/ all topical subheadings / all age subheadings

#9 "Random-Assignment"/ all topical subheadings / all age subheadings

#10 "Sample-Size"/ all topical subheadings / all age subheadings

#11 "Placebos"/ all topical subheadings / all age subheadings

#12 "Comparative-Studies"/ all topical subheadings / all age subheadings

#13 explode "Study-Design"/ all topical subheadings / all age subheadings

#14 explode "Experimental-Studies"/ all topical subheadings / all age subheadings

#15 explode "Community-Trials"/ all topical subheadings / all age subheadings #16

explode "Random-Sample"/ all topical subheadings / all age subheadings

#19 explode "Outcomes-(Health-Care)"/ all topical subheadings / all age subheadings

20 (research or clinical trial) in DT

#22 efficacy

#23 effectiveness

#24 (efficacy or effectiveness)

#25 double

#26 single

#27 triple

#28 blind*

#29 (double or single or triple) near1 blind*

#30 placebo*

#31 sham

#32 ask*

#33 sham or mask*

#34 intention

#35 to

#36 treat

#37 intention to treat

#38 control*

#39 trial*

#40 control* trial*

#41 #1 or #2 or #3 or #4 or #5 or #6 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15

or #16 or #17 or #18 or #19

#42 #20 or #24 or #29 or #30 or #33 or #37 or #40

#43 #41 or #42

#44 explode "Heart-Surgery"/ all topical subheadings / all age subheadings

#45 cardiac

#46 surgery

#47 cardiac surgery

#48 "Coronary-Artery-Bypass"/ all topical subheadings / all age subheadings

#49 "Aortic-Aneurysm-Thoracic"/ all topical subheadings / all age subheadings

#50 "Heart-Valve-Prosthesis"/ all topical subheadings / all age subheadings

#51 #44 or #47 or #48 or #49 or #50

#52 early

#53 extubation

#54 early near extubation

#55 removal

#56 endotracheal

#57 tube

#58 removal near endotracheal tube

#59 fast

#60 track

#61 fast track

#62 "Anesthesia-Recovery"/ all topical subheadings / all age subheadings

#63 #54 or #58 or #61 or #62

#64 #51 and #63

#65 #43 and #64

#66 explode "Child"/ all topical subheadings / all age subheadings

#67 explode "Adolescence"/ all topical subheadings / all age subheadings

#68 explode "Infant"/ all topical subheadings / all age subheadings

#69 #66 or #67 or #68

#70 explode "Adult"/ all topical subheadings / all age subheadings

#71 #69 not (#69 and #70)

#72 #65 not #71

APPENDIX D

EARLY EXTUBATION GUIDELINE

**PAGE/PAGES
EXCLUDED UNDER
INSTRUCTION
FROM
THE UNIVERSITY**

APPENDIX E

SYSTEMATIC REVIEW TABLES

Table 1 Characteristics of Included Studies

Study	Berry et al., 1998
Methods	<p>Randomized controlled trial</p> <p>Patients withdrawn from the study are not included in the analysis and reasons for withdrawal are detailed.</p> <p>Assessors were blinded for the diagnosis of myocardial ischaemia outcomes.</p>
Participants	<p>Elective coronary artery bypass graft (CABG) patients, with no ECG abnormalities, not older than 71 years, no digitalis therapy, no left or right bundle branch block, no morbid obesity (BMI>35), FEV1 or FVC >50%, no poor left ventricular function (CASS score of >15 or ejection fraction of <30%)</p> <p>Patients with < 10 hours of acceptable QRS complexes (i.e. not artefact, ventricular ectopics or bundle branch block) were excluded, from the analysis.</p>
Interventions	<p>Early extubation (within 8 hours) n = 43</p> <p>Conventional extubation (more than 8 hours) n = 42</p> <p>Premedication (see Additional Table 3) Induction (See Additional Table 4) Maintenance (see Additional Table 5)</p> <p>Profession of clinician deciding when to extubate: not given</p>
Outcomes	<p>- time to extubation (median and range)</p> <p>-mortality in hospital</p> <p>-rates of myocardial ischaemia measured by: non fatal MI (CK-MB levels, and daily ECGs for 3 days post surgery), ischaemic burden, area under the ST-deviation-time curve (AUC), average maximal ST-segment deviation during ischaemic episodes, systolic arterial pressure and heart rate at time of onset of episode compared with median values in preceding 25 minutes. The use of intra-aortic balloon pump and incidence of ventricular arrhythmias requiring treatment were also recorded.</p>
Notes	no respiratory outcomes investigated (apart from times to extubation), as study focused on ischaemia.
Allocation concealment	B

Study	Cheng et al., 1996a
Methods	<p>Randomized controlled trial</p> <p>All patients were included in the statistical analysis after allocation.</p> <p>Assessors were blinded for the diagnosis of atelectasis</p>
Participants	<p>Elective coronary artery bypass graft (CABG) patients under 75 years of age</p> <p>LV function grades I-IV</p> <p>No previous cardiac surgery</p> <p>no allergy to propofol,</p> <p>no left bundle branch block nor digitalis therapy, no documented myocardial infarction (MI) within previous 3 weeks, no active congestive cardiac failure, no inotropic therapy within 24 hours of surgery nor current intra aortic balloon pump (IABP), no severe hepatic disease, no renal insufficiency, no severe chronic obstructive pulmonary disease (COPD), no history of stroke nor seizure</p>
Interventions	<p>Early extubation (1-6 hours) n = 60</p> <p>Conventional extubation (day following surgery) n = 60</p> <p>Premedication (see Additional Table 3)</p> <p>Induction (See Additional Table 4)</p> <p>Maintenance (see Additional Table 5)</p> <p>Profession of clinician deciding when to extubate: not given</p>
Outcomes	<p>-mean time to extubation</p> <p>-mortality in ICU</p> <p>-30 day mortality rates</p> <p>-myocardial ischaemia rates</p> <p>-reintubation rates</p> <p>-atelectasis (measured at 24, 48 and 72 hours)</p> <p>-arterial blood gas measurements at 30 minutes and 4 hours post extubation,</p> <p>-Qs/Qt at 30 minutes and 4 hours post extubation,</p> <p>-time to when ready for discharge from ICU,</p> <p>-time to ready for discharge from hospital</p> <p>Other outcomes investigated/measured:</p> <p>-catecholamine stress response,</p> <p>-heart rate, blood pressure, cardiac output studies</p> <p>- use of drugs</p> <p>-respiratory measures : frequency, inspiratory and expiratory time, tidal volume, inspiratory flow rate, minute ventilation, central and obstructive apnoea, laboured breathing index, alveolar arterial oxygen gradient.</p> <p>-awareness and cognitive function,</p> <p>-blood loss,</p> <p>-shivering</p> <p>-respiratory and cardiac arrest</p> <p>-cerebral vascular accident</p>
Notes	
Allocation concealment	A

Study	Michalopoulos et al., 1998
Methods	<p>Randomized controlled trial</p> <p>Details of whether any patients were withdrawn from the study and how their data were analysed was not specified.</p>
Participants	<p>Elective coronary artery bypass (CABG) patients under 70 years of age, with ejection fraction of >35%, New York Heart Classification Class I to III, with normal pre-operative respiratory function (FVC > or = 75% and FEV1/FVC ratio > or = 75%)</p>
Interventions	<p>Early extubation (4-7 hours) n = 72 Conventional extubation (8 -14 hours) n = 72</p> <p>Premedication (see Additional Table 3) Induction (See Additional Table 4) Maintenance (see Additional Table 5)</p> <p>Profession of clinician deciding when to extubate: not given</p>
Outcomes	<p>-mean time to extubation -mortality rates -ischaemia rates, -rates of atelectasis -PCO2 levels on admission to ICU, post extubation and prior to discharge from ICU -ICU length of stay, - hospital length of stay Other outcomes/complications recorded: - stroke -ICU psychosis - Adult respiratory distress syndrome (ARDS) -Cardiac arrest -arrhythmia -pacing -shock -arterial hypertension -bleeding -infection -acute renal failure -jaundice-hyperbilirubinaemia</p>
Notes	
Allocation concealment	B

Study	Quasha et al., 1980
Methods	<p>Randomized controlled trial</p> <p>Outcomes of patients who failed to meet the early extubation criteria were detailed separately in the text.</p> <p>Assessor were blinded for the diagnosis of myocardial infarction.</p>
Participants	<p>Elective coronary artery bypass graft patients with normal and slightly impaired left ventricular function: Left ventricular end diastolic pressure (LVEDP) < 20 torr, right arterial pressure (RAP) <20 torr, cardiac index (CI) >1.9 L/min/m2, ejection fraction (EF) > 0.40)</p> <ul style="list-style-type: none"> - no new or uncontrolled arrhythmias - no MI within 6 weeks of surgery
Interventions	<p>Early extubation within 8 hours of surgery; n = 18</p> <p>Conventional extubation; n = 20</p> <p>Premedication (see Additional Table 3)</p> <p>Induction (See Additional Table 4)</p> <p>Maintenance (see Additional Table 5)</p> <p>Profession of clinician deciding when to extubate: not given</p>
Outcomes	<ul style="list-style-type: none"> -mean time to extubation -% extubated within 8 hours compared to % > 8 hours -reintubation rates -rates of ischaemia -atelectasis within 72 hours -pre surgery pulmonary shunt -pre extubation pulmonary shunt -ICU length of stay <p>Other outcomes/measures:</p> <ul style="list-style-type: none"> -cardiac output studies, - patient stress levels (plasma norepinephrine levels) -use of drugs -arrhythmias needing therapy -hypotension needing inotropic support -bleeding needing surgical control -cerebrovascular accident -pneumothorax -pneumonia
Notes	
Allocation concealment	B

Study	Reyes et al., 1997
Methods	<p>Randomized controlled trial</p> <p>Reasons for patients being withdrawn from the study are given in the text. Analysis for all the allocated patients compared with the patients who were not withdrawn has been provided by the author (unpublished data)</p> <p>Assessors were blinded for the diagnosis of myocardial ischaemia and atelectasis</p>
Participants	Elective, urgent and emergency coronary artery bypass graft (CABG) patients, CABG+valve, valve surgery
Interventions	<p>Early extubation (1st trial after 6 hours) n = 201 Conventional extubation (day after surgery) n =203</p> <p>Premedication (see Additional Table 3) Induction (See Additional Table 4) Maintenance (see Additional Table 5)</p> <p>Profession of clinician deciding when to extubate: Doctor</p>
Outcomes	<p>-mortality within 24 hours of surgery -30 day mortality -ischaemia rates -ventilation and intubation times -reintubation rates at 24 hours and within 7 days of surgery, and reasons for reintubation -atelectasis rates in the first 48 hours -atelectasis rates in the first week -ICU length of stay (median) Other outcomes/measures: APACHE II (acute physiology and chronic health evaluation) score at 24 hours -incidence of pneumonia - arrhythmias requiring therapy -hypertension -pulmonary oedema -low cardiac output state -new and persistent neurological deficit -acute renal failure -sepsis -sternal wound infection -need for reoperation for bleeding or rewiring of sternum -amount of blood loss in first 12 hours post surgery -use of vaso-active drugs</p>
Notes	
Allocation concealment	B

Study	Silbert et al., 1998
Methods	Randomized controlled trial Reasons why patients were withdrawn from the study are detailed in the text.
Participants	Elective coronary artery bypass graft patients, with good and moderate left ventricular function
Interventions	Early extubation (reduced dose fentanyl 15 mcg/kg) n = 38 Conventional extubation (conventional dose fentanyl 50 mcg/kg) Premedication (see Additional Table 3) Induction (See Additional Table 4) Maintenance (see Additional Table 5) Profession of clinician deciding when to extubate: not given
Outcomes	-time to extubation (median, range and Kaplan- Meier survival curve) -reintubation rates -rates of ischaemia (CPK-MB levels or new Q waves) -arterial blood gas values (no details of results given in text) -hospital length of stay (median, range and Kaplan- Meier survival curve) -ICU length of stay Other outcomes/measures: - APACHE II scores -use of drugs -complications -mean arterial blood pressure -emotional status
Notes	-ICU length of stay stated as outcome but no results given in text. Emotional status was the subject of another study and is not reported in this paper.
Allocation concealment	B

Table 2 Characteristics of excluded studies

Study	Reason for exclusion
Cheng (a) 1996	Report possibly of the same study as (Cheng 1996), focusing on outcomes related to costs and resource use.
Koslov 1995	Unclear whether the study is a randomized controlled trial

ADDITIONAL TABLES

Table 3 Premedication

Study ID	Study Group	Drugs	Dose	Route
Berry 1998	Early extubation	Diazepam	0.1mg kg ⁻¹	PO
	Conventional extubation	Diazepam	0.1mg kg ⁻¹	
Cheng 1996	Early extubation	Lorazepam	1-3mg	SL
	Conventional extubation	Lorazepam	1-3mg	SL
Michalopoulos 1998	Early extubation	Not stated		
	Conventional extubation			
Quasha 1980	Early extubation	Morphine	0.15mg/kg	IM
		Diazepam	0.15 mg/kg	PO
		atropine/scopolamine	not stated	IM
	Conventional extubation	Morphine	0.15mg/kg	IM
		Diazepam	0.15 mg/kg	PO
		atropine/scopolamine	not stated	IM
Reyes 1997	Early extubation	Not stated		
	Conventional extubation			
Silbert 1998	Early extubation	Paperveretum	0.3 mg/kg	IV
		Scopolamine	0.006mg/kg	IV
	Conventional extubation	Paperveretum	0.3 mg/kg	IV
		scopolamine	0.006mg/kg	IV

Table 4 Induction

Study ID	Study Group	Drugs	Dose	Route
Berry 1998	Early extubation	Fentanyl	15 mcg kg -1	IV
		Etomidate or diazepam	not given	IV
		Vecuronium	not given	IV
	Conventional extubation	Fentanyl	50 mcg kg -1	IV
		Etomidate or diazepam	not given	IV
		Vecuronium	not given	IV
Cheng 1996	Early extubation	Fentanyl	15 mcg/kg	IV
		Pancuronium	0.15 mg/kg	IV
	Conventional extubation	Fentanyl	50 mcg/kg	IV
		Pancuronium	0.15 mg/kg	IV
		midazolam	0.1mg/kg	IV
				IV
Michalopoulos 1998	Early extubation	Etomidate or Thiopentone	0.1-0.2 mg kg -1	IV
		Fentanyl	1-2 mg kg -1	IV
		Pancuronium	15-20 mcg kg -1	IV
		Midazolam	-1	IV
				IV
	Conventional extubation	Etomidate or Thiopentone	0.1 mg kg -1	IV
		2mg		IV
		Fentanyl	0.1-0.2 mg kg -1	IV
		Pancuronium	-1	IV
		Midazolam	1-2 mg kg -1	IV
			50 mcg kg -1	
			0.2 mg kg -1	
			0.1- 0.2 mg kg -1	
Quasha 1980	Early extubation	Thiopental	Not given	INH
	Conventional extubation	Nitrous oxide, oxygen, halothane		
		Thiopental		
		Nitrous oxide, oxygen, halothane		
Reyes 1997	Early extubation	Diazepam, midazolam or etomidate	Not given	Not given
	Conventional extubation	Diazepam, midazolam or etomidate		
Silbert 1998	Early extubation	Fentanyl	15mcg/kg	
		Pancuronium	0.1 mg/kg	
	Conventional extubation	Propofol	6-8mg/kg/hr	
		Fentanyl	50mcg/kg	
		Pancuronium	0.1 mg/kg	

Table 5 Maintenance

Study ID	Study Group	Drugs	Dose	Route
Berry 1998	Early extubation	Isoflurane in 100% oxygen vecuronium		INH
	Conventional extubation	Isoflurane in 100% oxygen vecuronium		INH
Cheng 1996	Early extubation	Isoflurane and Oxygen Propofol on CPB Midazolam pre CPB	0.2-1.5% 2-6 mg/kg/hr	INH INH IV
	Conventional extubation	Isoflurane peri-CPB Morphine Midazolam post CPB	0.2-1.5% prn 2-10 mg/hr 1-3mg/hr	IV INH IV IV
Michalopoulos 1998	Early extubation	Isoflurane or halothane or propofol Fentanyl Pancuronium (as needed for max. 2 hr)	0.5% 0.5% 2-4 mg/kg/hr 5mcg/kg total dose	INH INH IV IV IV
	Conventional extubation	Isoflurane or halothane or midazolam fentanyl Pancuronium (as needed for first 6h post op.)	0.5% 0.5% 0.1-0.2mg/kg 10-15 mcg/kg/hr	INH INH IV IV IV
Quasha 1980	Early extubation	Nitrous oxide, oxygen and halothane Pancuronium	Not given	INH IV
	Conventional extubation	Nitrous oxide, oxygen and halothane pancuronium		INH IV
Reyes 1997	Early extubation	High dose fentanyl Pancuronium or vecuronium	Not given	
	Conventional extubation	High dose fentanyl Pancuronium or vecuronium		
Silbert 1998	Early extubation	Propofol	3-4mg/kg/hr (more if necessary)	IV
	Conventional extubation	Midazolam (at beginning of CPB) Morphine (at end of CPB) (additional fentanyl or propofol as required and vecuronium	0.1mg/kg 0.1mg/kg	IV IV

APPENDIX F

Participant Information Sheets and Consent Forms

(headed paper)

Local Research Ethics Committee. Study No:

Study Title: Nurse Led Extubation of Cardiac Surgical Patients

Dear Sir/Madam,

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the enclosed information sheet carefully and discuss it with friends, and relatives if you wish. Please contact me and ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

I would like to emphasise that this study involves the researcher collecting information from your medical notes. The study will not affect your treatment in any way, either now or in the future.

If you would **not** like to take part in the study, please sign and date the enclosed consent forms. There are three identical ones; one for you to keep, one to be placed in your medical records and one for me, the researcher. Please bring the consent forms with you when you come to the hospital for your operation and give two copies to the nurse who admits you. Remember one copy is for you.

Thank you for taking the time to consider taking part in the study.

Yours faithfully,

Claire Hawkes,
Research Student, Oxford Brookes University
Staff Nurse [name] Unit, [name] Hospital.

(headed paper)

Local Research Ethics Committee. Study No:

Study Title: Nurse Led Extubation of Cardiac Surgical Patients

Information Sheet for Patients

Background to the study

The nurses on the [name] Unit at [name] Hospital have recently introduced an updated protocol to help them make the decision when to take patients off the ventilator, or breathing machine, after their heart surgery (this process is called extubation). The nurses have been making this decision for many years on the unit and are experienced in the practice.

The study is to evaluate the effectiveness of the protocol in guiding nurses' practice

What is the purpose of this study?

This study is an evaluation of the implementation of the protocol to standardise nurse led extubation on the unit and does not effect your treatment in any way, either now or in the future.

Who is doing the study?

The researcher is a staff nurse on the unit and is undertaking the study as part of PhD studies at Oxford Brookes University.

What will the study be used for?

The study will be useful for the nurses on the unit because it will provide information on the implementation of the protocol that can be used to inform future practice to maintain high standards of patient care or identify areas for improvement. The findings of the study will also be used in the researcher's PhD thesis and in papers written about the study for professional journals.

Why have I been chosen?

All patients who are being admitted for coronary artery bypass graft surgery over the next year are being invited to give permission for the researcher to use information routinely recorded in their medical and nursing notes for the study.

Do I have to take part?

It is up to you to decide whether or allow your medical notes to be used for this study. If you decide to take part please keep this information sheet to keep and to sign the enclosed consent form. There are three copies of the consent form, one for you, one to go in your medical records and one for the researcher. Please give two copies to the nurse who admits when you arrive at the hospital for your operation. If you decide to take part you are still free to withdraw at any time and without giving a reason. Please write to the researcher at the contact address given below.

What is involved in participating in the study?

All you need to do to take part in the study is to sign the consent forms and give two copies to the nurse who admits you for your operation. The researcher will then be able to look at your notes once you have been discharged and use the relevant information in the study.

What information from my medical notes will be used in the study?

Information recorded routinely on the nurses' observation charts, which is where they record things like your blood pressure and heart rate will be used. The information that will be collected is about how long you were on the ventilator, how much oxygen you needed through the a face mask and for how long afterwards, how many blood samples the nurses took to check your oxygen levels and how much fluid they gave you through your drip. I will also look at the nurses' and doctors' written notes for information about what operation you had, how long you were on the heart-lung bypass machine, your extubation and details of your recovery, including complications, if any, and how long before you went home from hospital. Information about whether you had to come back into hospital within a month will also be collected.

Confidentiality

All the information from your medical notes will be treated in the strictest confidence. All information will be anonymised. The anonymised information will be held on computer in accordance with the Data Protection Act and Oxford Brookes University Data Protection Guidelines. No information will be given in the thesis, publications or reports arising from this study, which could identify you or any other participants.

Who has reviewed the study?

The Local Research Ethics Committee for [area] has reviewed and approved this study.

Contact for further information

If you have any questions please contact the researcher, Claire Hawkes either by telephone: xxxx or by email: [email address] or by writing to the following address; OCHRAD, Oxford Brookes University, xxxxxx.

Local Research Ethics Committee Study No:

Study Title: Nurse Led Extubation of Cardiac Surgical Patients

Invitation to Participate

Dear

I would like to invite you to take part in the above study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the enclosed information sheet carefully and discuss it with friends, relatives and your manager if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

If you decide you would like to take part, please fill in the reply slip below and return it to me, either in person or via my pigeonhole on the unit. If you prefer you can return it by post to me at the following address: xxxxx
Please reply by 7th October 2002.

If you do not wish to participate you need take no further action and you do not need to give any reason to me or anyone else why you have made this decision, as participation is entirely voluntary.

Yours Sincerely,

Claire Hawkes

Dear Claire,

I have read and considered the invitation to participate and information sheet for the study, Nurse Led Extubation of Cardiac Surgical Patients (LREC Study No: xxx) and I would like to take part. Please contact me to arrange a convenient time and place for the interview.

Signed _____

Print name please _____

Contact telephone number _____

Local Research Ethics Committee Study No:
Study Title: Nurse Led Extubation of Cardiac Surgical Patients

Information Sheet for Participants

What is the purpose of this study?

This study is an evaluation of the implementation of a guideline to standardise nurse led extubation on the [name] Unit at the John Radcliffe Hospital. The researcher is undertaking the study as part of PhD studies at Oxford Brookes University. The findings will also be useful for the nurses on the unit because it will provide information on the implementation of the guideline that can be used to inform future practice.

Why have I been chosen?

As part of the study interviews are being conducted with clinicians and managers who have been involved with the implementation of the extubation guideline to explore the process involved. A variety of people involved are being invited to be interviewed to give a their different perspectives.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you please keep this information sheet and return the reply sheet on the invitation letter to the researcher. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What is involved in participating in the study?

The researcher will contact you to arrange a suitable time and place for an interview. At the beginning of the interview you will have the opportunity to raise any questions about the study and you will be asked to sign a consent form. With your permission the interview will be tape-recorded. The interview will take approximately 45 minutes and you will be asked for your views of the implementation process of the extubation guideline.

Confidentiality

All the information you give will be treated in the strictest confidence. I will not tell anyone you have agreed to participate in the study. All information will be anonymised. The anonymised information will be held on computer in accordance with the Data Protection Act and Oxford Brookes University Data Protection Guidelines. No information will be given in the thesis, publications or reports arising from this study, which could identify you or any other participants.

Who has reviewed the study?

The Local Research Ethics Committee for [area] has reviewed and approved this study.

Contact for further information

If you have any questions please contact the researcher, Claire Hawkes either by leaving a message in her pigeon hole on the unit or by telephone: xxx or by email: [email address].

(Form to be on headed paper)

Study Number:

CONSENT FORM

Title of Project: **Standardising Nurse Led Extubation of Cardiac Surgical Patients**

Name of Researcher: Claire Hawkes

Please initial box

1. I confirm that I have read and understand the information sheet dated
(version.....) for the above study and have had the opportunity to ask questions.

☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time,
without giving any reason, or my legal rights being affected.

☐

3. I agree that the interview can be tape-recorded and transcribed.

☐

4. I agree that any words I may say during the interview can be used, anonymously, in the
presentation of the research.

☐

5. I agree to take part in the above study.

☐

_____	_____	
Name of Participant	Date	Signature

_____	_____	
Name of Person taking consent (if different from researcher)	Date	Signature

_____	_____	
Researcher	Date	Signature

1 for participant ; 1 for researcher.

APPENDIX G

PUBLICATIONS

**PAGE/PAGES
EXCLUDED UNDER
INSTRUCTION
FROM
THE UNIVERSITY**